rev. May 3, 1999

Patent Terms and Extensions

I. 35 U.S.C. 154 - Patent Term and Term Extension

35 U.S.C. 154. Contents and term of patent.

(a) IN GENERAL.-

(1) CONTENTS.-Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.

(2) TERM.-Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed.

(3) PRIORITY.-Priority under section 119, 365(a), or 365(b) of this title shall not be taken into account in determining the term of a patent.

(4) SPECIFICATION AND DRAWING.-A copy of the specification and drawing shall be annexed to the patent and be a part of such patent.

(b) TERM EXTENSION.-

(1) INTERFERENCE DELAY OR SECRECY ORDERS.-If the issue of an original patent is delayed due to a proceeding under section 135(a) of this title, or because the application for patent is placed under an order pursuant to section 181 of this title, the term of the patent shall be extended for the period of delay, but in no case more than 5 years.

(2) EXTENSION FOR APPELLATE REVIEW.-If the issue of a patent is delayed due to appellate review by the Board of Patent Appeals and Interferences or by a Federal court and the patent is issued pursuant to a decision in the review reversing an adverse determination of patentability, the term of the patent shall be extended for a period of time but in no case more than 5 years. A patent shall not be eligible for extension under this paragraph if it is subject to a terminal disclaimer due to the issue of another patent claiming subject matter that is not patentably distinct from that under appellate review.

(3) LIMITATIONS.-The period of extension referred to in paragraph (2)-

(A) shall include any period beginning on the date on which an appeal is filed under section 134 or 141 of this title, or on which an action is commenced under section 145 of this title, and ending on the date of a final decision in favor of the applicant;

(B) shall be reduced by any time attributable to appellate review before the expiration of 3 years from the filing date of the application for patent; and

(C) shall be reduced for the period of time during which the applicant for patent did not act with due diligence, as determined by the Commissioner.

(4) LENGTH OF EXTENSION.-The total duration of all extensions of a patent under this subsection shall not exceed 5 years.

(c) CONTINUATION.-

(1) DETERMINATION.-The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20 - year term as provided in subsection (a), or 17 years from grant subject to any terminal disclaimers.

(2) REMEDIES.-The remedies of sections 283, 284, and 285 of this title shall not apply to Acts which -

(A) were commenced or for which substantial investment was made before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act; and

(B) became infringing by reason of paragraph (1).

(3) REMUNERATION.-The acts referred to in paragraph (2) may be continued only upon the payment of an equitable remuneration to the patentee that is determined in an action brought under chapter 28 and chapter 29 (other than those provisions excluded by paragraph (2)) of this title.

For applications filed on or after June 8, 1995, utility and plant patents (other than those granted on reissue applications) will be granted for a term which begins on the date the patent issues and ends twenty years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under 35 U.S.C. 120, 121, or 365(c), twenty years from the earliest effective U.S. filing date. Patents on design applications will be granted for a term of 14 years which begins on the date the patent issues.

A patent granted on an application which resulted from an international application after compliance with 35 U.S.C. 371 will have a term which ends twenty years from the filing date of the international application.

A continuation or a continuation - in - part application of an international application filed under 35 U.S.C. 363 designating the United States will have a term which ends twenty years from the filing date of the parent international application.

Foreign priority under 35 U.S.C. 119(a) - (d), 365(a), or 365(b) is not considered in determining the term of a patent. Likewise, priority under 35 U.S.C. 119(e) to one or more U.S. provisional applications is not considered in the calculation of the twenty year term.

TRANSITIONAL RULES

All patents that are in force on June 8, 1995, or that issue on an application that was filed before June 8, 1995, automatically have a term that is the greater of the twenty year term discussed above or seventeen years from the patent grant. This provision affects all patents that are in force on June 8, 1995, and all patents issued thereafter on applications filed prior to June 8, 1995. The terms of these patents are, of course, subject to reduction by any applicable terminal disclaimers.

EXPIRATION DATE OF PATENTS WITH TERMINAL DISCLAIMERS

To determine the "original expiration date" of a patent subject to a terminal disclaimer, it is necessary to examine the language of the terminal disclaimer in the patent file history. If the disclaimer disclaims the terminal portion of the term of the patent which would

extend beyond the expiration date of another patent, then the expiration date of the other patent determines the expiration date of the patent subject to the terminal disclaimer. Therefore, the expiration date may be different from that printed on the face of the patent when the patent issued, if the expiration date of the other patent changed because of the Uruguay Round Agreements Act (URAA) and the subsequent amendment to 35 U.S.C. 154. However, if the terminal disclaimer disclaims the terminal portion of the patent subsequent to a certain date, and does not state that the date is the expiration date of another patent, then the expiration date is the date specified.

A. Term Extensions for Delays Within the PTO

The twenty year patent term may be extended for a maximum of five years for delays in the issuance of the patent due to interferences, secrecy orders and/or successful appeals to the Board of Patent Appeals and Interferences or the Federal courts in accordance with 35 U.S.C. 154(b) and 37 CFR 1.701. Extensions for successful appeals are limited in that the patent must not be subject to a terminal disclaimer. Further, the period of extension will be reduced by any time attributable to appellate review within three years of the filing date of the application and the period of extension for appellate review will be reduced by any time during which the applicant did not act with due diligence. The patent term extension that may be available under 35 U.S.C. 156 for premarket regulatory review is separate from and will be added to any extension that may be available under 35 U.S.C. 154.

Examiners make no decisions regarding patent term extensions. Extensions under 35 U.S.C. 156 are handled by the Office of the Deputy Assistant Commissioner for Patent Policy and Projects. Extensions related to interferences, secrecy order and successful appellate review will be calculated by PALM and will be printed on the Notice of Allowance and Issue Fee Due. Any patent term extension granted as a result of administrative delay pursuant to 35 U.S.C. 154(b) and 37 CFR 1.701 will also be printed on the face of the patent in generally the same location as the terminal disclaimer information. The term of a patent will be readily discernible from the face of the patent (i.e., from the filing date, continuing data, issue date and any patent term extensions printed on the patent).

If applicant disagrees with the patent term extension information printed on the notice of allowance, applicant may request review by way of a petition under 37 CFR 1.181. To avoid loss of patent term, however, any such petitions filed during the pendency of the application will not be decided until after issuance of the patent. If the petition is granted, a Certificate of Correction pursuant to 37 CFR 1.322 will be issued. If an error is noted after the patent issues, patentee may seek correction of the patent term extension granted by filing a request for a Certificate of Correction pursuant to 37 CFR 1.322.

Petitions and Certificates of Correction regarding patent term extensions under 35 U.S.C. 154(b) should be addressed to AAssistant Commissioner for Patents, Box DAC, Washington, D.C. 20231@ and will be decided in the Special Program Law Office.

II. Patent Term Extension Under 35 U.S.C. 156

The right to a patent term extension based upon regulatory review is the result of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 St. 1585 (Codified at 21 U.S.C. 355(b),(j),(l), 35 U.S.C. 156, 271, 282) (Hatch-Waxman Act). The act sought to eliminate two distortions to the normal "patent term produced by the requirement that certain products must receive premarket regulatory approval." *Eli Lilly & Co. v. Medtronic Inc.*, 496 U.S. 661, 669, 15 USPQ2d 1121, 1126 (1990). The first distortion was that the patent owner loses patent term during the early years of the patent because the product cannot be commercially marketed without approval from a regulatory agency. The second distortion occurred after the end of the patent term. Competitors delayed entry into the market because they were not allowed to begin testing and performing other activities necessary for their own approval process until the patent had expired.

The part of the act codified as 35 U.S.C. 156 was designed to create new incentives for the research and development of certain products subject to premarket government approval by a regulatory agency. Patent term extension under 35 U.S.C. 156 restores a portion of the patent term lost as a result of regulatory agency premarketing testing and approval requirements for drugs products, food additives, color additives, medical devices, animal drugs, and veterinary biological products. Under specified circumstances, the statute authorizes the extension of the term of a patent which claims these federally regulated products or methods of using or manufacturing these federally regulated products.

The term "approved product" is used herein to refer to an active ingredient of a drug product, a medical device, or a food or color additive which has been approved by a regulatory agency for commercial use or sale. The rights derived from extension of the patent are limited to the approved product, if the approved product is claimed, the method of use of the approved product, if a method of use of the approved product is claimed, and/or the method of manufacturing the approved product, if the method of manufacturing the approved product is claimed. 35 U.S.C. 156(b). Accordingly, if the patent claims other products in addition to the approved product, the exclusive patent rights to the additional products expire with the original expiration date of the patent.

In exchange for the 35 U.S.C. 156 patent term extension provisions, Congress legislatively overruled *Roche Products v. Bolar Pharmaceuticals*, 733 F.2d 858, 221 USPQ 937 (Fed. Cir. 1984) as to products covered by 35 U.S.C. 271(e), and provided that it shall not be an act of infringement, for example, to make and test a patented drug solely for the purpose of developing and submitting information for an Abbreviated New Drug Application (ANDA). 35 U.S.C. 271(e)(1). See Donald O. Beers, *Generic and Innovator Drugs: A Guide to FDA Approval Requirements*, Fourth Edition, Aspen Law & Business, 1995, 4.3[2] for a discussion of the Hatch-Waxman Act and infringement litigation. Furthermore, Congress provided that an ANDA cannot be filed until five years after the approval date of the product if the active ingredient or a salt or ester of the active

ingredient had not been previously approved under section 505(b) of the Federal Food, Drug and Cosmetic Act. 21 U.S.C. 355(j)(4)(D)(ii). *See also*, Lourie, *Patent Term Restoration: History, Summary, and Appraisal*, 40 Food, Drug and Cosmetic L. J. 351, 353-60 (1985). *See also*, Lourie, *Patent Term Restoration*, 66 J. Pat. Off. Soc'y 526 (1984).

On November 16, 1988, 35 U.S.C. 156 was amended by Public Law 100-670, essentially to add animal drugs and veterinary biologics to the list of products that can form the basis of patent term extension. Animal drug products which are primarily manufactured through biotechnology are excluded from the provisions of patent term extension.

On December 3, 1993, 35 U.S.C. 156 was further amended to provide for interim extension of a patent where a product claimed by the patent was expected to be approved, but not until after the original expiration date of the patent. Public Law 103-179, Section 5.

An application for the extension of the term of a patent under 35 U.S.C. 156 must be submitted by the owner of record of the patent or its agent within the sixty day period beginning on the date the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. See 35 U.S.C. 156(d)(1). The Patent and Trademark Office initially determines whether the application is formally complete and whether the patent is eligible for extension. The statute requires the Commissioner of Patents and Trademarks to notify the Secretary of Agriculture or the Secretary of Health and Human Services of the submission of an application for extension of patent term which complies with the section, and to submit to the Secretary a copy of the application. After receipt of the application from the Commissioner, the Secretary will determine the length of the applicable regulatory review period and notify the Commissioner of the determination. If the Commissioner determines that the patent is eligible for extension, the Commissioner calculates the length of extension for which the patent is eligible under the appropriate statutory provision and issues an appropriate Certificate of Extension.

Patent term extensions provided by private relief legislation, and public laws other than as enacted by 35 U.S.C. 156, such as 35 U.S.C. 155 and 155A, are not addressed herein.

A. Eligibility Requirements - Which Patents May be Extended Under 35 U.S.C. 156

35 U.S.C. 156. Extension of patent term.

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if -

(1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;

(2) the term of the patent has never been extended under subsection (e)(1) of this section;

(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);

(4) the product has been subject to a regulatory review period before its commercial marketing or use;

(5)(A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or

use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;

(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; or

(C) for purposes of subparagraph (A), in the case of a patent which --

(i) claims a new animal drug or a veterinary biological product which (I) is not covered by the claims in any other patent which has been extended, and (II) has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and

(ii) was not extended on the basis of the regulatory review period for use in non-food-producing animals,

the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the Aapproved product.@

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(f) For purposes of this section:

(1) The term Aproduct@ means:

(A) A drug product.

(B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

(2) The term Adrug product@ means the active ingredient of--

(A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act), or

(B) a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques, including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

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37 CFR 1.710. Patents subject to extension of the patent term.

(a) A patent is eligible for extension of the patent term if the patent claims a product as defined in paragraph (b) of this section, either alone or in combination with other ingredients that read on a composition that received permission for commercial marketing or use, or a method of using such a product, or a method of manufacturing such a product, and meets all other conditions and requirements of this subpart.

(b) The term Aproduct@ referred to in paragraph (a) of this section means C

(l) The active ingredient of a new human drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient; or

(2) The active ingredient of a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) that is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes including site specific genetic manipulation techniques, including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient; or

(3) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

35 U.S.C. 156(a) sets forth what patents can be extended and the conditions under which they may be extended. 37 CFR 1.710 further addresses the patents that may be

extended, and 37 CFR 1.720 describes the conditions under which a patent may be extended. As set forth in 35 U.S.C. 156 and 37 CFR 1.710, a patent which claims a human drug product, medical device, or food or color additive first approved for marketing or use after September 24, 1984, or an animal drug or veterinary biological product (which was not primarily manufactured through biotechnology) first approved for marketing or use after November 16, 1988, may qualify for patent term extension. Furthermore, 35 U.S.C. 156(a)(1) - (5) require the applicant to establish that:

(1) the patent has not expired before an application under subsection (d) was filed (this may be an application for patent term extension under subsection (d)(1) or an application for interim extension under subsection (d)(5));

(2) the patent has never been extended under subsection (e)(1);

(3) the application for extension, which includes details relating to the patent and to the time spent in securing regulatory agency approval, is submitted by the owner of record of the patent or its agent to the Office within sixty days of regulatory agency approval of the commercial marketing application (except as provided in 35 U.S.C. 156(d)(5));

(4) the product has been subject to a regulatory review period within the meaning of 35 U.S.C. 156(g) before its commercial marketing or use; and

(5) the approval is the first permitted commercial marketing or use of the product (35 U.S.C. 156(a)(5)(A)), except in the case of human drug products manufactured using recombinant DNA technology, it is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent (35 U.S.C. 156(a)(5)(B)); in the case of a new animal drug or a veterinary biological product, the provisions of 35 U.S.C. 156(a)(5)(C) apply.

No other patent term can be extended for the same regulatory review period for the product. 35 U.S.C. 156(c)(4).

37 CFR 1.720 sets forth the conditions for extension of the patent term and essentially restates the requirements of 35 U.S.C. 156(a). The requirements are as follows:

37 CFR 1.720. Conditions for extension of patent term.
The term of a patent may be extended if:
(a) the patent claims a product or a method of using or manufacturing a product as defined in ' 1.710;
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Under 35 U.S.C. 156(a), patents eligible for extension of patent term are those which claim a "product" as defined in 35 U.S.C. 156(f)(1), either alone or in combination with other ingredients, that reads on a composition that received permission for commercial marketing or use, or a method of using such a product, or a method of manufacturing such a product, and meets all other conditions and requirements of the statute. The term "claims" is not synonymous with "infringed by." A patent which claims a metabolite of an approved drug does not claim the approved drug. *Hoechst-Roussel Pharmaceuticals Inc. v. Lehman*, 109 F.3d 756, 759, 42 USPQ2d 1220, 1223 (Fed. Cir. 1997); U.S. Patent No. 4,631,286.

The term "product" means:

(l) The active ingredient of a new human drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient; or

(2) The active ingredient of a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) that is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes including site specific genetic manipulation techniques, including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient; or

(3) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

A product as described in item (1) or (2) is considered a "drug product." See 21 CFR 60.3(b) for definitions of terms such as active ingredient, color additive, food additive, human drug product, and medical device.

Essentially, a "product," as defined by 35 U.S.C. 156 and 37 CFR 1.710, is a "drug product," medical device, food additive, or color additive requiring Food and Drug Administration or Department of Agriculture (Plant and Animal Inspection Service) approval prior to commercial marketing or use. Animal biological products are approved by the Plant and Animal Inspection Service of the Department of Agriculture.

A "drug product" means the active ingredient found in the final dosage form prior to administration of the product to the patient, not the resultant form the drug may take after administration. In this regard, a drug in the ester form which is used for oral administration is a different drug product from the same active moiety in a salt form which is administered by injection, even though both the salt and the ester are used to treat the same disease condition. The ester form is a different active ingredient from the salt form. Both the ester and the salt active ingredient may each support an extension of patent term of different patents provided the acid itself has not previously been approved. See *Glaxo Operations UK Ltd. v. Quigg*, 706 F.Supp. 1224, 1232-33, 10 USPQ2d 1100, 1107 (E.D. Va. 1989), *aff'd*, 894 F.2d 392, 13 USPQ2d 1628 (Fed. Cir. 1990).

The term "active ingredient" has a broad definition. The term Aactive ingredient@ is defined in 21 CFR 60.3(b)(2) as A(2) any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or of animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.@ Accordingly, the approved product need not itself contain the active ingredient claimed by the patent. For example, if when the approved product is dissolved to create a solution for intravenous administration, a product claimed in the patent is created, and the product so created is administered to the patient to provide the desired effect, the broad definition of active ingredient permits the patent claiming the active ingredient so created to be eligible for patent term extension. See U.S. Patent Nos. 4,258,041 and 4,808,614. An active ingredient of a drug is the

ingredient in the drug product that becomes therapeutically active when administered. *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 393, 13 USPQ2d 1628, 1629 (Fed. Cir. 1990), *but c.f., Abbott Laboratories v. Young*, 920 F.2d 984, 989 n.7 (D.C. Cir. 1990), cert denied, 112 S. Ct. 76 (1991) (The court rejected the argument of *Glaxo* in considering whether Abbott was entitled to exclusivity).

Furthermore, a "drug product" is the active ingredient of a particular new drug, rather than the entire composition of the drug product approved by the Food and Drug Administration. See *Fisons plc v. Quigg*, 1988 U.S. Dist. LEXIS 10935, 8 USPQ2d 1491, 1495 (D.D.C. 1988), *aff'd*, 876 F.2d 99, 110, 10 USPQ2d 1869, 1870 (Fed. Cir. 1989).

For purposes of patent term extension, a patent is considered to claim "a drug product" at least in those situations where the patent claims the active ingredient per se, or claims a composition or formulation which contains the active ingredient(s) and reads on the composition or formulation approved for commercial marketing or use.

37 CFR 1.720. Conditions for extension of patent term.

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(b) The term of the patent has never been previously extended except for any interim extension issued pursuant to ' l.760;

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37 CFR 1.720(b) explains the statutory requirement of 35 U.S.C. 156(a)(2). An interim extension issued pursuant to ' 1.760 is an interim extension under 35 U.S.C. 156(e)(2).

37 CFR 1.720. Conditions for extension of patent term.

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(c) an application for extension is submitted in compliance with ' 1.740;

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37 CFR 1.720(c) parallels the statutory requirement of 35 U.S.C. 156(a)(3). The requirements of 37 CFR 1.740 are discussed in ' II(B)(2).

37 CFR 1.720. Conditions for extension of patent term.

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(d) The product has been subject to a regulatory review period as defined in 35 U.S.C. 156(g) before its commercial marketing or use;

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37 CFR 1.720(d) parallels the statutory requirement set forth in 35 U.S.C. 156(a)(4). The regulatory review period must have been a regulatory review period defined by 35 U.S.C. 156(g). A regulatory review period under section 510(k) of the Federal Food, Drug and Cosmetic Act is not a regulatory review period which gives rise to eligibility for patent term extension under 35 U.S.C. 156. *In re Nitinol Medical Technologies Inc.*, 17 USPQ2d 1492, 1492-1493 (Comm'r Pat. & Tm. 1990). See also *Baxter Diagnostics v. AVL Scientific Corp.*, 798 F. Supp. 612, 619-620, 25 USPQ2d 1428, 1434 (C.D. Cal.

1992)(Congress intended only Class III medical devices to be eligible for patent term extension).

If the product is alleged to be a medical device, then regulatory review must have occurred under section 515, and not section 505, of the Federal Food, Drug and Cosmetic Act. If the product is alleged to be a drug product then regulatory review must have occurred under section 351, 505(b), or 507 of the Federal Food, Drug and Cosmetic Act. Drug products are not reviewed under section 515 of the aforementioned Act. See U.S. Patent Nos. 4,710,532 and 4,824,893.

37 CFR 1.720. Conditions for extension of patent term.

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(e) The product has received permission for commercial marketing or use and --

(1) The permission for the commercial marketing or use of the product is the first received permission for commercial marketing or use under the provision of law under which the applicable regulatory review occurred, or

(2) In the case of a patent other than one directed to subject matter within ' 1.710(b)(2) claiming a method of manufacturing the product that primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use is the first received permission for the commercial marketing or use of a product manufactured under the process claimed in the patent,

(3) In the case of a patent claiming a new animal drug or a veterinary biological product that is not covered by the claims in any other patent that has been extended, and has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and was not extended on the basis of the regulatory review period for use in non-food-producing animals, the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

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37 CFR 1.720(e) parallels 35 U.S.C. 156(a)(5), and sets forth that the approval under the relevant provision of law must have been the first permitted marketing or use of the product under the provision of law, unless the product is for use in food producing animals as explained below. See *In re Patent Term Extension Application, U.S. Patent No. 3,849,549*, 226 USPQ 283, 284 (Comm'r Pat. & Tm. 1985). If the product is a human drug product, then the approval of the active ingredient must be the first permitted commercial marketing or use of the active ingredient as a single entity or in combination with another active ingredient under the provision of law under which regulatory review occurred.

Approval of a product containing two ingredients can not be used to extend a patent claiming only an active ingredient when the use of the active ingredient has been previously approved under the same provision of law. However, where a product which contains multiple active ingredients is approved, if any one active ingredient has not been previously approved, a patent that claims a newly approved active ingredient as well as previously approved active ingredients can be extended. See *In re Alcon Laboratories Inc.*, 13 USPQ2d 1115, 1121 (Comm'r Pat. & Tm. 1989) for examples of products having different combinations of active ingredients. A different ratio of hormones is not a different active ingredient for purposes of 35 U.S.C. 156. See the prosecution history of

the patent term extension application for U.S. Patent No. 4,780,451 (application for patent term extension denied where FDA had previously approved a mixture of the same hormones for use in a food producing animal). Furthermore, an approved product having two active ingredients, which are not shown to have a synergistic effect or have pharmacological interaction, will not be considered to have a single active ingredient made of the two active ingredients. See the application for patent term extension of U.S. Patent No. 4,529,601.

As to 35 U.S.C. 156 (a)(5)(C), which is addressed in 37 CFR 1.720 (e)(3), the term of a patent directed to a new animal drug or veterinary biological product may be extended based on a second or subsequent approval of the active ingredient provided all the following conditions exist:

(a) the patent claims the drug or product;

(b) the drug or product is not covered by the claims in any other patent that has been extended;

(c) the patent term was not extended on the basis of the regulatory review period for use in non-food producing animals; and

(d) the second or subsequent approval was the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal. In this case, the application must be filed within sixty days of the first approval for administration to a food-producing animal.

For animal drugs or products, prior approval for use in a non-food producing animal will not make a patent ineligible for patent term extension based upon a later approval of the drug or product for use in food producing animals, if the later approval is the first approval of the drug or product for use in food producing animals.

37 CFR 1.720 Conditions for extension of patent term.

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(f) The application is submitted within the sixty-day period beginning on the date the product first received permission for commercial marketing or use under the provisions of law under which the applicable regulatory review period occurred; or in the case of a patent claiming a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the application for extension is submitted within the sixty-day period beginning on the date of the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; or in the case of a patent that claims a new animal drug or a veterinary biological product that is not covered by the claims in any other patent that has been extended, and said drug or product has received permission for the commercial marketing or use in non-food-producing animals, the application for extension is submitted within the sixty-day period beginning on the date of the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal;

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37 CFR 1.720(f) further explains 35 U.S.C. 156(a)(3) to the extent that it requires that the application comply with the requirements of 35 U.S.C. 156 (d)(1).

37 CFR 1.720 Conditions for extension of patent term.

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(g) The term of the patent has not expired before the submission of an application in compliance with

' 1.741;

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37 CFR 1.720(g) parallels the requirements of 35 U.S.C. 156(a)(1).

37 CFR 1.720. Conditions for extension of patent term.

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(h) No other patent term has been extended for the same regulatory review period for the product.

If more than one application for patent term extension is filed based upon a single regulatory review period, election will be required of a single patent.

B. Application Requirements
(1) Who May Apply

35 U.S.C. 156. Extension of patent term.

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(d)(1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Commissioner.

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37 CFR 1.730. Applicant for extension of patent term.

Any application for extension of a patent term must be submitted by the owner of record of the patent or its agent and must comply with the requirements of ' 1.740.

35 U.S.C. 156(d)(1) requires that the application for extension of the patent term must be submitted by the owner of record of the patent or its agent. If the application is filed by an assignee, the application papers should refer to the reel and frame number of the recorded assignment. 37 CFR 1.740(b)(1) requires that the person signing the declaration aver that he is the owner, an official of a corporate owner authorized to obligate the corporation, or a patent attorney or agent authorized to practice before the Patent and Trademark Office who has general authority from the patent owner of record to act on behalf of the owner in patent matters. Accordingly, if a licensee of the patent owner is authorized by the patent owner to file a patent term extension application, the licensee may file the application, but the declaration must be signed by the patent owner or an attorney or agent having general authority from the patent owner of record to act on behalf of the patent owner on patent matters.

If the applicant for patent term extension was not the marketing applicant before the regulatory agency, then there must be an agency relationship between the patent owner and the marketing applicant during the regulatory review period. See the application for patent term extension in U.S. Patent No. 4,848,336. In that application, a license taken by the marketing applicant from the patent owner 18 days before product approval was considered insufficient to make the marketing applicant an agent of the patent owner. To

show that a patent term extension applicant that was not also the marketing applicant is authorized to rely upon the activities of the marketing applicant before the Food and Drug Administration or the Department of Agriculture, the applicant for patent term extension should obtain a letter from the marketing applicant specifically authorizing such reliance and include that letter with the patent term extension application.

(2) Application Contents

35 U.S.C. 156. Extension of patent term.

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(d)(1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Commissioner. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. The application shall contain --

(A) the identity of the approved product and the Federal statute under which regulatory review occurred;

(B) the identity of the patent for which an extension is being sought and the identity of each claim of such patent which claims the approved product or a method of using or manufacturing the approved product;

(C) information to enable the Commissioner to determine under subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Commissioner and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the period of the extension under subsection (g);

(D) a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities; and

(E) such patent or other information as the Commissioner may require.

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The phrase Athe applicant@ in 35 U.S.C. 156(d)(1)(D) is a reference to the applicant for patent term extension. The only parties that may be an applicant are Athe owner of record of the patent or its agent.@ 35 U.S.C. 156(d)(1). See the application for patent term extension for U.S. Patent No. 4,848,336, where an extension was not granted, based in part on the fact that the marketing applicant was not an agent of the patent owner. In that application, the FDA=s response to a Freedom of Information Act request had supplied some of the information required for the application for patent term extension.

37 CFR 1.740 sets forth the requirements for a formal application for extension of patent term. The requirements include:

37 CFR 1.740. Application for extension of patent term.

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(a)(1) A complete identification of the approved product as by appropriate chemical and generic name, physical structure or characteristics;

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37 CFR 1.740(a)(1) requires a complete identification of the approved product, as by appropriate chemical and generic name, physical structure or characteristics, to enable the Commissioner to make a determination of whether the patent claims the approved product, or a method of using or manufacturing the approved product.

37 CFR 1.740. Application for extension of patent term.

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(a)(2) A complete identification of the Federal statute including the applicable provision of law under which the regulatory review occurred;

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37 CFR 1.740(a)(2) requires a complete identification of the Federal statute including the applicable provision of law. When the regulatory review of the product took place under more than one Federal statute, each appropriate statute should be listed. This could apply to a situation where a human biological product is tested under an investigational new drug (IND) application pursuant to the Federal Food, Drug, and Cosmetic Act, but is approved under the Public Health Service Act; or to a situation where approval is sought for use of a particular medical device with a specific drug product which may require approval under more than a single provision of law. The product that forms the basis of an application for patent term extension must be either a medical device or a drug product; it cannot be a combination of those separate products. See the file history of U.S. Patent No. 4,428,744 for an example of the application of this principle.

37 CFR 1.740. Application for extension of patent term.

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(a)(3) An identification of the date on which the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred;

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The date that a product receives permission for commercial marketing or use is generally the mailing date of the letter from FDA or the Department of Agriculture indicating regulatory approval, even if the letter indicates that further regulatory approval is required before such commercial sale or use may begin. *Unimed, Inc. v. Quigg*, 880 F.2d 675, 12 USPQ2d 1644 (Fed. Cir. 1989) (An application for patent term extension was not timely filed where the application was filed within sixty days Drug Enforcement Agency rescheduling of a controlled substance, but beyond sixty days from FDA approval). For a food additive, the approval date is generally the effective date stated in the regulation and the date the regulation is published.

37 CFR 1.740. Application for extension of patent term.

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(a)(4) In the case of a drug product, an identification of each active ingredient in the product and as to each active ingredient, a statement that it has not been previously approved for commercial marketing or use under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, or the Virus-Serum-Toxin Act, or a statement of when the active ingredient was approved for commercial marketing or use (either alone or in combination with other active ingredients) the use for which it was approved, and the provision of law under which it was approved;

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37 CFR 1.740(a)(4) provides that for drug products, each active ingredient must be identified. It also requires an indication of the use for which the product was approved. For each active ingredient, a statement must be made that either (1) the active ingredient was not previously approved for commercial marketing or use under the Federal Food, Drug and Cosmetic Act, or (2) that the active ingredient was approved for commercial marketing or use (either alone or in combination with other active ingredients) and the provision of law under which it was approved. The information is especially necessary for

a determination of eligibility where, for example, the application is based on a second or subsequent approval of an active ingredient, but the first approval for administration to a food-producing animal.

37 CFR 1.740. Application for extension of patent term.

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(a)(5) A statement that the application is being submitted within the sixty day period permitted for submission pursuant to ' l.720(f) and an identification of the date of the last day on which the application could be submitted;

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If the sixty-day period ends on a Saturday, Sunday or Federal holiday, then the last day on which the application could be submitted will be considered to be the next business day following the Saturday, Sunday or Federal holiday. See 37 CFR 1.7. However, applicants are cautioned to avoid filing an application for patent term extension on the last day for filing to avoid the application being denied because the filing deadline was inadvertently missed.

37 CFR 1.740. Application for extension of patent term.

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(a)(6) A complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue, and the date of expiration;

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The date of expiration should be according to the law (35 U.S.C. 154) in force at the time of filing of the application for patent term extension.

37 CFR 1.740. Application for extension of patent term.

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(a)(7) A copy of the patent for which an extension is being sought, including the entire specification (including claims) and drawings;

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A photocopy of the patent is acceptable.

37 CFR 1.740. Application for extension of patent term.

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(a)(8) A copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate issued in the patent;

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Photocopies of the required documents are acceptable. If there is no disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate, applicants are encouraged to state that there is none.

37 CFR 1.740. Application for extension of patent term.

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(a)(9) A statement that the patent claims the approved product or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which each applicable patent claim reads on the approved product or method of using or manufacturing the approved product;

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The statement must list each applicable patent claim and demonstrate the manner in which each applicable patent claim reads on the approved product or a method of using or manufacturing the approved product. The showing should clearly explain how each listed claim reads on the approved product. For example, where a generic chemical structure is used in the claim to define the claimed invention, a listing of variables and substituents which correspond to the approved product is appropriate. Where a claim uses the "means for" language permitted by 35 U.S.C. 112, paragraph 6, reference to the column and line number of the patent text and any drawing reference numbers, as well as a description of any relevant equivalents, is also appropriate.

37 CFR 1.740 Application for extension of patent term.

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(a)(10) A statement beginning on a new page, of the relevant dates and information pursuant to 35 U.S.C. 156(g) in order to enable the Secretary of Health and Human Services or the Secretary of Agriculture, as appropriate, to determine the applicable regulatory review period as follows:

(i) For a patent that claims a human drug, antibiotic, or human biological product, the effective date of the investigational new drug (IND) application and the IND number; the date on which a new drug application (NDA) or a Product License Application (PLA) was initially submitted and the NDA or PLA number and the date on which the NDA was approved or the Product License issued;

(ii) For a patent claiming a new animal drug, the date a major health or environmental effects test on the drug was initiated and any available substantiation of the date or the date of an exemption under subsection (j) of section 512 of the Federal Food, Drug, and Cosmetic Act became effective for such animal drug; the date on which a new animal drug application (NADA) was initially submitted and the NADA number; and the date on which the NADA was approved;

(iii) For a patent claiming a veterinary biological product, the date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective; the date an application for a license was submitted under the Virus-Serum-Toxin Act; and the date the license issued;

(iv) For a patent claiming a food or color additive, the date a major health or environmental effects test on the additive was initiated and any available substantiation of that date; the date on which a petition for product approval under the Federal Food, Drug and Cosmetic Act was initially submitted and the petition number; and the date on which the FDA published a Federal Register notice listing the additive for use;

(v) For a patent claiming a medical device, the effective date of the investigational device exemption (IDE) and the IDE number, if applicable, or the date on which the applicant began the first clinical investigation involving the device if no IDE was submitted and any available substantiation of that date; the date on which the application for product approval or notice of completion of a product development protocol under section 515 of the Federal Food, Drug and Cosmetic Act was initially submitted and the number of the application or protocol; and the date on which the application was approved or the protocol declared to be completed.

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Where there is no regulatory event to reflect the commencement of the testing or approval phase of the regulatory review period, applicant should include in the application the dates on which applicant initiated either the approval or the testing phases. Applicant should also include an explanation of the reasonable basis on which applicant concludes that these dates are the relevant dates. For example, when the clinical trials are conducted outside of the United States, the testing phase for a medical device begins on the date the clinical investigation involving the device was begun. An applicant should include an explanation as to why the date claimed is the date on which such clinical investigations had commenced. If the applicant has any means of substantiating the date, that information

should be included in the application.

37 CFR 1.740. Application for extension of patent term.

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(a)(11) A brief description beginning on a new page of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities;

*****

37 CFR 1.740(a)(11) requires a brief description of the activities of the marketing applicant before the regulatory agency. This description should include an identification of significant communications of substance with the FDA or Department of Agriculture and the dates related to such communications. For example, these activities would include the dates of the submissions of new data to the FDA, communications between FDA and the applicant with respect to the appropriate protocols for testing the product, and communications between FDA and the applicant that are attempts to define the particular requirements for premarketing approval for this particular product. The applicant is not required to establish the existence of due diligence during the regulatory review period in order to have a complete application.

As stated above, the marketing applicant must have been an agent of the patent owner, if not the same entity as the patent owner. Accordingly, the Office will not assist the patent owner in obtaining information required in an application for patent term extension from the marketing applicant. It is sufficient that the description of the activities briefly identify those significant activities undertaken by the marketing applicant directed toward regulatory approval, and a submission of insignificant details or identification of non-substantive communications is not required.

37 CFR 1.740. Application for extension of patent term.

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(a)(12) A statement beginning on a new page that in the opinion of the applicant the patent is eligible for the extension and a statement as to the length of extension claimed, including how the length of extension was determined;

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37 CFR 1.740(a)(12) requires the extension applicant to state the length of extension claimed and show how the length of extension was calculated, including whether the 14-year patent term remainder limit of 35 U.S.C. 156(c)(3) or the two or three year patent term extension limit of 35 U.S.C. 156(g)(6)(C) applies.

37 CFR 1.740. Application for extension of patent term.

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(a)(13) A statement that applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to the determination of entitlement to the extension sought (see ' 1.765);

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37 CFR 1.740(a)(13) requires the extension applicant to disclose any information material to the determination of entitlement to the extension sought. The applicant has a duty to disclose to the Secretary of Agriculture (where the regulatory review was conducted by the USDA) as well as to the Commissioner and the Secretary of Health and

Human Services.

37 CFR 1.740. Application for extension of patent term.

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(a)(14) The prescribed fee for receiving and acting upon the application for extension (see ' 1.20(j));

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Care should be taken to use the current fee. A deposit account authorization may be used.

37 CFR 1.740. Application for extension of patent term.

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(a)(15) The name, address, and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed;

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If the address given is intended to change the address of all correspondence, including maintenance fee reminders, a change of address should also be filed. A change of address must be signed by the patent applicant, the assignee of the entire interest, or an attorney or agent or record. 37 CFR 1.33(a). Accordingly, if the patent term extension application is signed by the marketing applicant, as an agent of the patent owner, a proper power of attorney from the patent owner to an attorney for the marketing applicant would be necessary for the attorney for the marketing applicant to be able to sign a change of address. Normally only communications regarding the application for patent term extension will be sent to the address specified in the patent term extension application. A fax number should also be provided.

37 CFR 1.740. Application for extension of patent term.

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(a)(16) A duplicate of the application papers, certified as such;

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No special form is required for the certification, and the applicant's attorney or agent may simply state that the copy is certified to be a duplicate of the application for patent term extension. Furthermore, applicants are encouraged to supply three additional copies (a total of five) since five copies are required for Office processing of the application.

37 CFR 1.740. Application for extension of patent term.

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(a)(17) An oath or declaration as set forth in paragraph (b) of this section.

(b) Any oath or declaration submitted in compliance with paragraph (a) of this section must be signed by the owner of record of the patent or its agent, specifically identify the papers and the patent for which an extension is sought and aver that the person signing the oath or declaration:

(l) Is the owner, an official of a corporate owner authorized to obligate the corporation, or a patent attorney or agent authorized to practice before the Patent and Trademark Office and who has general authority from the owner to act on behalf of the owner in patent matters.

(2) Has reviewed and understands the contents of the application being submitted pursuant to this section;

(3) Believes the patent is subject to extension pursuant to ' 1.710;

(4) Believes an extension of the length claimed is justified under 35 U.S.C. 156 and the applicable regulations; and

(5) Believes the patent for which the extension is being sought meets the conditions for extension of the term of a patent as set forth in ' 1.720.

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The oath or declaration must be signed by the patent owner, or a patent attorney or patent agent having generally authority from the owner to act on behalf of the patent owner in patent matters, and must accompany the application as a part thereof. The certified duplicate of the application papers must include a true copy of the oath or declaration. If the patent owner is an assignee, then the reel and frame number of the recorded assignment should be stated in the application for patent term extension. Additionally, if an officer of a corporation is signing on behalf of the corporation, then the title of the officer should be specified. If the person signing the oath or declaration is a patent attorney or patent agent of the patent owner, then a power of attorney should be included if the attorney or agent is not already of record.

(3) Filing Date Requirements - Complete Application

35 U.S.C. 156. Extension of patent term.

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(d)(1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Commissioner. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use.

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37 CFR 1.741. Filing date of application.

(a) The filing date of an application for extension of a patent term is the date on which a complete application is received in the Patent and Trademark Office or filed pursuant to the "Certificate of Mailing or Transmission" procedures of 37 CFR 1.8 or "Express Mail" provisions of 37 CFR 1.10. A complete application shall include:

(1) An identification of the approved product;

(2) An identification of each Federal statute under which regulatory review occurred;

(3) An identification of the patent for which an extension is being sought;

(4) An identification of each claim of the patent which claims the approved product or a method of using or manufacturing the approved product;

(5) Sufficient information to enable the Commissioner to determine under 35 U.S.C. 156 subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Commissioner and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the length of the regulatory review period; and

(6) A brief description of the activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities.

(b) If any application submitted pursuant to this section is held to be incomplete, applicant may seek to have this holding reviewed under ' 1.181.

(a) What Filing Date is Accorded

An application for patent term extension under 35 U.S.C. 156 may be filed by mail

addressed to the Assistant Commissioner for Patents, Box **Patent Ext.**, Washington, D.C. 20231 or may be hand carried to the Special Program Law Office in the Office of the Deputy Assistant Commissioner for Patent Policy and Projects. As stated in MPEP ' 502, a hand carried application should be accompanied by a receipt that can be returned to the applicant.

As set forth in 37 CFR 1.741(a), the filing date of an application for patent term extension is the date on which a complete application is received in the Patent and Trademark Office or filed pursuant to the certificate of mailing provisions of 37 CFR 1.8 or the Express Mail provisions of 37 CFR 1.10. See MPEP ' 512 for suggested formats for a certificate of mailing under 37 CFR 1.8. The term "complete application" is defined in 37 CFR 1.741(a) and is an application meeting the requirements set forth in 35 U.S.C. 156(d)(1). For the establishment of a filing date, the distinction between the requirements of 37 CFR 1.740 and the requirements of section 37 CFR 1.741 are important. While the requirements of 37 CFR 1.740 may be satisfied outside the sixty day filing period, the requirements of 37 CFR 1.741 are mandated by 35 U.S.C. 156 and must be satisfied within the sixty day filing period for the establishment of the filing date. The Office will consider each of these statutory requirements to be satisfied in an application which provides sufficient information, directed to each requirement, to act on the application, even though further information may be desired by the PTO or the regulatory agency before a final determination of eligibility and length of patent term extension is made.

Patent term extension applications should not be filed by facsimile, but correspondence setting forth a change of address and other papers relating to a patent term extension may be sent by facsimile to the Special Program Law Office.

(b) Deadline for Filing an Application under 35 U.S.C. 156(d)(1)

An application for patent term extension under 35 U.S.C. 156(d)(1) may only be filed within the sixty-day period beginning on the date the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred. The statutory time period is not extendable and cannot be waived or excused. See U.S. Patent No. 4,486,425 (application for patent term extension filed after the end of the sixty-day period and was therefore denied). The sixty-day period begins on the regulatory agency approval date which marks the end of the regulatory review period. The statute takes into account only the regulatory review carried out by the Food and Drug Administration or the Department of Agriculture and no other government obstacles to marketing or use. See *Unimed, Inc. v. Quigg*, 888 F.2d 826, 828, 12 USPQ2d 1644, 1646 (Fed. Cir. 1989). For drug products the approval date is the date of a letter by the Food and Drug Administration indicating that the application has been approved, even if the letter requires further action before the drug can be marketed. *Mead Johnson Pharmaceutical Group v. Bowen*, 838 F.2d 1332, 1336, 6 USPQ2d 1565, 1568 (D.C. Cir. 1988). For food or color additives, the relevant date is the effective date of the regulation or order, which is set forth in the regulation or order, and which is generally the date that the regulation or order is published, e.g., in the

Federal Register. See 21 U.S.C. 348(e).

(c) Filing Window for an Application under 35 U.S.C. 156(d)(5)

A first application for interim extension under 35 U.S.C. 156(d)(5) must be filed within the period beginning six months and ending fifteen days before the patent is due to expire. Each subsequent application for interim extension must be filed during the period beginning sixty days before and ending thirty days before the expiration of the preceding interim extension. 35 U.S.C. 156(d)(5)(C). An interim extension granted under 35 U.S.C. 156(d)(5) terminates sixty days after permission for commercial marketing or use of the product is granted, except, if within the sixty-day period any additional information needed for an application for patent term extension under 35 U.S.C. 156(d)(1) is submitted, the patent may be further extended. 35 U.S.C. 156(d)(5)(E). The additional information required to be submitted includes the fee for an application for patent term extension under 35 U.S.C. 156(d)(1) and identification of the date the product received permission for commercial marketing or use and a statement that the application is being submitted within sixty days of such date and identification of the last date that the application could be submitted. See 37 CFR 1.740(a)(3) and (5). However, if the product is not approved within the period of interim extension, a new request for interim extension must be filed and another interim extension granted to keep the patent in force. An applicant is generally limited to four one-year interim extensions.

(d) Filing of a Request for an Extension under 35 U.S.C. 156(e)(2)

A request for an interim extension under 35 U.S.C. 156(e)(2) should be made at least three months before the patent is due to expire. 37 CFR 1.760.

C. PTO Processing

35 U.S.C. 156. Extension of patent term.

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(e) (1) A determination that a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the application for the extension.

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(1) Informal Application

37 CFR 1.740. Application for extension of patent term.

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(c) If any application for extension of patent term submitted pursuant to this section is held to be informal, applicant may seek to have that holding reviewed by filing a petition with the required fee, as necessary, pursuant to ' 1.181, ' l.182 or ' l.183, as appropriate, within such time as may be set in the notice that the application has been held to be informal, or if no time is set, within one month of the date on which the application was held informal. The time periods set forth herein are subject to the provisions of 37 CFR ' 1.136.

If the application does not meet all the formal requirements of 37 CFR 1.740(a), the applicant will be notified of the informalities and may seek to have that holding reviewed

under 37 CFR 1.740(c) by filing a petition with the required fee, as necessary, pursuant to 37 CFR 1.181, 1.182, or 1.183, as appropriate, within such time as may be set in the notice that the application has been held to be informal, or if no time is set, within one month of the date on which the application was held informal. The time periods set forth therein are subject to the provisions of 37 CFR 1.136.

Note, however, that if the application satisfies the requirements of 37 CFR 1.741, the application filing date will have been established as provided therein, even if the application is held to be informal under 37 CFR 1.740.

(2) Eligibility Determination

35 U.S.C. 156. Extension of patent term.

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(e) (1) A determination that a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the application for the extension.

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37 CFR 1.750. Determination of eligibility for extension of patent term.

A determination as to whether a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the application for extension filed in compliance with ' 1.740 or ' 1.790. This determination may be delegated to appropriate Patent and Trademark Office officials and may be made at any time before the certificate of extension is issued. The Commissioner or other appropriate officials may require from applicant further information or make such independent inquiries as desired before a final determination is made on whether a patent is eligible for extension. In an application for extension filed in compliance with ' 1.740, a notice will be mailed to applicant containing the determination as to the eligibility of the patent for extension and the period of time of the extension, if any. This notice shall constitute the final determination as to the eligibility and any period of extension of the patent. A single request for reconsideration of a final determination may be made if filed by the applicant within such time as may be set in the notice of final determination or, if no time is set, within one month from the date of the final determination. The time periods set forth herein are subject to the provisions of ' 1.136.

The determination as to whether a patent is eligible for an extension will normally be made solely from the representations contained in the application for patent term extension. However, further information may be required or inquiry made of applicant before a final determination is made on whether a patent is eligible for extension. In circumstances where further information is required by the Office, the applicant will be given a time period within which to respond. The failure to provide a response within the time period provided may result in a final determination adverse to the granting of an extension of patent term unless the response period is extended. An extension of time to respond may be requested under the provisions of 37 CFR 1.136. Under appropriate circumstances, e.g., if time is of the essence for a particular reason, a request for information may contain a statement that the provisions of 37 CFR 1.136(a) are not available. The intentional failure to provide the information requested may result in an adverse final determination.

A final determination may be made at any time after an application is filed. A single request for reconsideration of a final determination may be filed within one month or

within such other time period set in the final determination. A notice will be mailed to applicant containing the determination as to eligibility of the patent for extension and the period of time of the extension of the term, if any. This notice shall constitute the final determination as to eligibility and any period of extension of the patent term. If no response to the notice of final determination is received, the certificate of patent term extension will be issued in due course.

(a) Interim Extension of Patent Term During the Processing of the Application

35 U.S.C. 156. Extension of patent term.

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(e) (2) If the term of a patent for which an application has been submitted under subsection (d)(1) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Commissioner shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

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37 CFR 1.760. Interim extension of patent term under 35 U.S.C. 156(e)(2).

An applicant who has filed a formal application for extension in compliance with ' 1.740 may request one or more interim extensions for periods of up to one year each pending a final determination on the application pursuant to ' 1.750. Any such request should be filed at least three months prior to the expiration date of the patent. The Commissioner may issue interim extensions, without a request by the applicant, for periods of up to one year each until a final determination is made. The patent owner or agent will be notified when an interim extension is granted and notice of the extension will be published in the *Official Gazette* of the Patent and Trademark Office. The notice will be recorded in the official file of the patent and will be considered as part of the original patent. In no event will the interim extensions granted under this section be longer than the maximum period of extension to which the applicant would be eligible.

If the original term of the patent for which extension is sought will expire before a final decision to issue a certificate of extension can be made, and a determination is made that the patent is eligible for extension, 35 U.S.C. 156 provides that the Commissioner may issue an interim extension of the patent term for up to one year pending a final decision on the application for extension. Should additional time be necessary, additional interim extensions of up to one year may be granted by the Commissioner. The length of any interim extension is discretionary with the Commissioner so long as it is for one year or less. Its length should be set to provide time for completion of any outstanding requirements. See *In re Reckitt & Colman Products Ltd.*, 230 USPQ 369, 372 (Comm'r Pat. & Tm. 1986). The Commissioner may issue an interim extension under 35 U.S.C. 156(e)(2) with or without a request from the applicant.

Where a determination is made that the patent is not eligible for patent term extension, an interim extension of the patent term is not warranted under 35 U.S.C. 156(e)(2). See *In re Alcon Laboratories Inc.*, 13 USPQ2d 1115, 1123 (Comm'r. Pat. & Tm. 1989).

Where an interim extension has been granted and it is subsequently determined that the patent is not eligible for patent term extension, the interim extension may be vacated *ab initio* as ineligible under 35 U.S.C. 156(e)(2). See *Reckitt*, 230 USPQ at 370.

While 37 CFR 1.760 provides that a request for an interim extension by the applicant

"should" be filed three months prior to the expiration of the patent, this time frame is not mandatory. Any request filed within a shorter period of time will be considered, upon a proper showing where it is not possible to make an earlier request. However, for an interim extension to be granted, the application for extension, in compliance with 37 CFR 1.741, must have been filed prior to the expiration date of the patent. In no event will an interim extension be granted for a period of patent term extension longer than the period of extension to which the patent would be eligible.

A notice of each interim extension granted will be issued to the applicant for patent term extension. The notice will be recorded in the official file of the patent and will be considered as part of the original patent. Notification of the issuance of the interim extension will be published in the *Official Gazette*.

(b) Interim Extension of Patent Term Before Product Approval

35 U.S.C. 156. Extension of patent term.

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(d)(5)(A) If the owner of record of the patent or its agent reasonably expects that the applicable regulatory review period described in paragraphs (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect, the owner or its agent may submit an application to the Commissioner for an interim extension during the period beginning 6 months, and ending 15 days before such term is due to expire. The application shall contain-

(i) the identity of the product subject to regulatory review and the Federal statute under which such review is occurring;

(ii) the identity of the patent for which interim extension is being sought and the identity of each claim of such patent which claims the product under regulatory review or a method of using or manufacturing the product;

(iii) information to enable the Commissioner to determine under subsection (a)(1), (2), and (3) the eligibility of a patent for extension;

(iv) a brief description of the activities undertaken by the applicant during the applicable regulatory review period to date with respect to the product under review and the significant dates applicable to such activities; and

(v) such patent or other information as the Commissioner may require.

(B) If the Commissioner determines that, except for permission to market or use the product commercially, the patent would be eligible for an extension of the patent term under this section, the Commissioner shall publish in the Federal Register a notice of such determination, including the identity of the product under regulatory review, and shall issue to the applicant a certificate of interim extension for a period of not more than 1 year.

(C) The owner of record of a patent, or its agent, for which an interim extension has been granted under subparagraph (B), may apply for not more than 4 subsequent interim extensions under this paragraph, except that, in the case of a patent subject to subsection (g)(6)(C), the owner of record of the patent, or its agent, may apply for only 1 subsequent interim extension under this paragraph. Each such subsequent application shall be made during the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension.

(D) Each certificate of interim extension under this paragraph shall be recorded in the official file of the patent and shall be considered part of the original patent.

(E) Any interim extension granted under this paragraph shall terminate at the end of the 60-day period beginning on the date on which the product involved receives permission for commercial marketing or use,

except that, if within that 60-day period the applicant notifies the Commissioner of such permission and submits any additional information under paragraph (1) of this subsection not previously contained in the application for interim extension, the patent shall be further extended, in accordance with the provisions of this section-

(i) for not to exceed 5 years from the date of expiration of the original patent term; or

(ii) if the patent is subject to subsection (g)(6)(C), from the date on which the product involved receives approval for commercial marketing or use.

(F) The rights derived from any patent the term of which is extended under this paragraph shall, during the period of interim extension-

(i) in the case of a patent which claims a product, be limited to any use then under regulatory review;

(ii) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent then under regulatory review; and

(iii) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the product then under regulatory review.

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37 CFR 1.790. Interim extension of patent term under 35 U.S.C. 156(d)(5) .

(a) An owner of record of a patent or its agent who reasonably expects that the applicable regulatory review period described in paragraph (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect may submit one or more applications for interim extensions for periods of up to one year each. The initial application for interim extension must be filed during the period beginning 6 months and ending 15 days before the patent term is due to expire. Each subsequent application for interim extension must be filed during the period beginning 60 days before and ending 30 days before the expiration of the preceding interim extension. In no event will the interim extensions granted under this section be longer than the maximum period of extension to which the applicant would be entitled under 35 U.S.C. 156(c).

(b) A complete application for interim extension under this section shall include all of the information required for a formal application under ' 1.740 and a complete application under ' 1.741. Sections (a)(1), (a)(2), (a)(4), and (a)(6) - (a)(17) of ' 1.740 and ' 1.741 shall be read in the context of a product currently undergoing regulatory review. Sections (a)(3) and (a)(5) of ' 1.740 are not applicable to an application for interim extension under this section.

(c) The content of each subsequent interim extension application may be limited to a request for a subsequent interim extension along with a statement that the regulatory review period has not been completed along with any materials or information required under '' 1.740 and 1.741 that are not present in the preceding interim extension application.

37 CFR 1.791. Termination of interim extension granted prior to regulatory approval of a product for commercial marketing or use.

Any interim extension granted under 35 U.S.C. 156(d)(5) terminates at the end of the 60-day period beginning on the date on which the product involved receives permission for commercial marketing or use. If within that 60-day period the patent owner or its agent files an application for extension under '' 1.740 and 1.741 including any additional information required under 35 U.S.C. 156(d)(1) not contained in the application for interim extension, the patent shall be further extended in accordance with the provisions of 35 U.S.C. 156.

If a patent that claims a product which is undergoing the approval phase of regulatory review as defined by 35 U.S.C. 156(g)(1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), and (5)(B)(ii) is expected to expire before approval is granted, patent term extension is available under 35 U.S.C. 156(d)(5). The application for patent term extension that must be submitted is generally the same as would be filed had the product been approved, except that the approval date is not required to be set forth. Once the product is approved, the application must be converted to an application for patent term extension

under 35 U.S.C. 156(d)(1) to obtain patent term extension under that subsection.

Processing of an application for interim patent term extension under 35 U.S.C. 156(d)(5) is performed in the Special Program Law Office and is similar to other applications for patent term extension, except that the Office is not required to seek the advice of the relevant regulatory agency. However, the relevant agency is normally consulted before an interim extension is granted or before the application for interim extension is denied. The fee for an application for patent term extension under 35 U.S.C. 156(d)(5) is set forth in 37 CFR 1.20(j)(2), and the fee for a subsequent application is set forth in 37 CFR 1.20(j)(3). Applications for interim extension are maintained in the same manner as applications for patent term extension. As required by 35 U.S.C. 156(d)(5)(B), a determination that a patent is eligible for extension under 35 U.S.C. 156, but for regulatory approval, is published in the Federal Register. A sample order granting interim extension follows:

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE COMMISSIONER OF PATENTS AND TRADEMARKS

In re ____	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No.____	:	INTERIM EXTENSION

On __, patent owner __, filed an application under 35 U.S.C. ' 156(d)(5) for interim extension of the term of U.S. Patent No. __. The patent claims the active ingredient __ in the human drug product "___." The application indicates that the product is currently undergoing a regulatory review before the Food and Drug Administration for permission to market or use the product commercially. The original term of the patent expired on ___. On ___, the patent was granted an first interim extension under 35 U.S.C. ' 156(d)(5) for a period of one year.

Review of the application indicates that except for receipt of permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. ' 156. Since it is apparent that the regulatory review period may extend beyond the date of expiration of the patent, as extended by the first interim extension, a second interim extension of the patent term under 35 U.S.C. ' 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. ' 156(d)(5) of the term of U.S. Patent No. __ is granted for a period of one year from the extended expiration date of the patent.

As seen from the example given, a series of one-year interim extensions may be granted if requested in a timely manner (in the window of time between thirty and sixty days before the extended expiration date).

An interim extension granted under 35 U.S.C. 156(d)(5) terminates sixty days after permission for commercial marketing or use of the product is granted, except, if within the sixty day period any additional information needed for an application for patent term extension under 35 U.S.C. 156(d)(1) is submitted, the patent may be further extended. 35 U.S.C. 156(d)(5)(E).

(c) First Letter to Regulatory Agency

It is the responsibility of the Commissioner of Patents and Trademarks to decide whether an applicant has satisfied the requirements of the statute and whether the patent qualifies for patent term extension. The regulatory agency possesses expertise and records regarding some of the statutory requirements and has certain direct responsibilities under 35 U.S.C. 156 for determining the length of the regulatory review period. Consequently, to facilitate eligibility decisions and permit the regulatory agency and the Office to carry out their responsibilities under 35 U.S.C. 156, both the Food and Drug Administration and the Department of Agriculture have entered into an agreement of cooperation with the Patent and Trademark Office. *Memorandum of Understanding Between the Patent and Trademark Office and the Food and Drug Administration*, 52 Fed. Reg. 17830 (May 12, 1987); *Memorandum of Understanding Between the Patent and Trademark Office and the Animal and Plant Health Inspection Service*, 54 Fed. Reg. 26399 (June 23, 1989), 1104 OG 18 (July 11, 1989). The agreements establish the procedures whereby the regulatory agency assists the Office in determining a patent's eligibility for patent term restoration under 35 U.S.C. 156. It also establishes procedures for exchanging information between the regulatory agency and the Office regarding regulatory review period determinations, due diligence petitions and informal regulatory agency hearings under the law. The Animal and Health Inspection Service of the Department of Agriculture is responsible for assisting the Office in determining the eligibility of a patent for patent term extension when the patent is claiming a veterinary biological product that has been subject to the Virus-Serum-Toxin Act (21 U.S.C. 151-59), and for determining the regulatory review period of the veterinary biological product. The Secretary of Health and Human Services of the Food and Drug Administration is responsible for assisting the Office in determining the eligibility of patents claiming any other product for which regulatory review gives rise to eligibility for patent term extension. 21 CFR 60.10.

Under the agreement, the regulatory agency, upon receipt of a written request from the Office, will convey to the Office the following information regarding eligibility for extension: (1) whether a product has undergone a regulatory review period within the meaning of 35 U.S.C. 156(g) prior to commercialization; (2) whether the marketing permission was for the first permitted commercial marketing or use of that product, or, in the case of recombinant DNA technology, whether such commercial marketing or use was the first permitted under the process claimed in the patent; and (3) whether the patent term extension application was submitted within sixty days after the product was approved, as well as any other relevant information. Similarly, upon a request by the Office and the receipt of a copy of the application for patent term extension, the regulatory agency will determine the length of the regulatory review period for the approved product.

The procedures covered by the agreement extend from the date of the Office's request for information on eligibility to the resolution of due diligence petitions and informal hearings. The regulatory review period determination is not final until due diligence petitions and informal hearings, if any, have been resolved. A certificate for extension of

the term of a patent may not issue from the Office until the regulatory review period determination is final unless an interim extension appears warranted under 35 U.S.C. 156(d)(5) and (e)(2).

If there are no clear reasons to deny eligibility, or if the applicant has been notified of any informalities and it is anticipated that the informalities will be corrected or explained, a Afirst letter@ to the regulatory agency is prepared. Even if there are questions concerning eligibility, the proceedings continue on the basis of assumed eligibility until such time as a determination is actually made. The Afirst letter@ requests assistance on the eligibility determination from the FDA or Department of Agriculture and enables the regulatory agency to start gathering information for subsequent proceedings before the regulatory agency under 35 U.S.C. 156. A copy of the application is included with this letter. This letter is **not** the request for the determination of the applicable regulatory review period.

The Afirst letter@ to the regulatory agency may include the following text and is copied to the patent term extension applicant:

The attached application for patent term extension of U.S. Patent No. ____, was filed ___, under 35 U.S.C. ' 156.

The assistance of your Office is requested in confirming that the product identified in the application, ___, has been subject to a regulatory review period within the meaning of 35 U.S.C. ' 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. ' 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. ' 156.

(d) Regulatory Agency Reply to First Letter

The regulatory agency reply to the "first letter," requesting assistance on the eligibility determination, is usually in the form of a written response: (1) verifying whether the product was subject to a regulatory review period before its commercial marketing or use; (2) stating whether the permission for commercial marketing or use of the product after the regulatory review period is the first permitted commercial marketing or use of the product either under the provision of law under which the regulatory review occurred, or under the process claimed in the patent when the patent claims a method of manufacturing the product that primarily uses recombinant DNA technology in the manufacture of the product; (3) informing the Office whether the patent term restoration application was submitted within sixty days after the product was approved for marketing or use; and (4) providing the Office with any other information relevant to the Office determination of whether a patent related to a product is eligible for patent term extension. As is the case with all correspondence between the Office and the regulatory agency, a copy is also sent to the applicant. While the Office has primary responsibility for the eligibility

determination, the information described above is often helpful. Because the regulatory agency possesses information which is not readily available to the Office, this assistance on the part of the regulatory agency enables both the Office and the agency to process applications efficiently and to conserve resources.

(e) Second Letter to Regulatory Agency, Request for Determination of Length of Regulatory Review Period

Upon receipt of a reply from the regulatory agency to the Afirst letter@ from the Office requesting assistance on determining eligibility, the preliminary eligibility decision (not the final decision) is made as to whether the patent is eligible for an extension of its term. The response from the regulatory agency will usually inform the Office as to whether the permission for commercial marketing and use of the product on which the application for patent term extension is based is the first such approval for that product. The regulatory agency provides information regarding the date of the NDA or other approval to permit a determination as to whether the application was filed within the sixty day statutory period. This information is then compared with the related information from the application. If no major discrepancies are found and if appropriate, a Asecond letter@ requesting a determination of the length of the regulatory review period of the product is prepared and mailed to the regulatory agency not later than sixty days after the Office receipt date of the response from the regulatory agency, unless the patent is determined not to be eligible for patent term extension. In the interest of efficiency, if the patent is determined to be ineligible for patent term extension, the Office will dismiss the application rather than request a determination of the regulatory review period. *In re Allen & Hansbury, Ltd.*, 227 USPQ 955, 960 n. 9 (Comm'r Pat. & Tm. 1985). The certified copy of the application for patent term extension is sent to the regulatory agency along with the Asecond letter.@ The Asecond letter@ states that, subject to final review, the patent is considered eligible for patent term restoration and requests a determination of the applicable regulatory review period.

The Asecond letter@ to the regulatory agency may include the following text and is also copied to the patent term extension applicant:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. ___, which issued ___. The application was filed on ___, under 35 U.S.C. ' 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. ' 156(d)(2)(A).

(f) Regulatory Agency Determination of the Length of the Regulatory Review Period

Under 35 U.S.C. 156, the regulatory agency is responsible for the determination of the length of the regulatory review period for the approved product on which the application

for patent term extension is based. The determination by the regulatory agency is made based on the application as well as the official regulatory agency records for the approved product. See, e.g., 21 CFR Ch. 1, Subpart C. The determination of the length of the regulatory review period is solely the responsibility of the regulatory agency. *Aktiebolaget Astra v. Lehman*, 71 F.3d 1578, 1580-81, 37 USPQ2d 1212, 1214-15 (Fed. Cir. 1995); U.S. Patent No. 4,215,113.

Once the determination has been made, the regulatory agency publishes the information in the Federal Register and forwards a letter to the Office with the same information. Included in both the Federal Register Notice and letter to the Office is the total length of the regulatory review period and the relevant dates on which the determination is based. Both the letter to the Office and the Federal Register Notice separates the total regulatory period into the initial or testing phase and the final approval phase. This provides the Office with the information necessary to determine the actual length of extension for which the patent may be eligible. The Federal Register Notice also sets a date, 180 days after publication of the notice, as a deadline for filing written comments concerning any of the information set forth in the notice, or a petition for a determination regarding whether the marketing applicant has acted with due diligence during the regulatory review period. The letter to the Office makes clear that the determination does not take into account the issue date of the patent nor does it exclude one-half of the testing phase.

(g) Due Diligence Determination

If a due diligence petition is filed during the 180-day period following publication of the regulatory agency determination of the regulatory review period, the regulatory agency (e.g. FDA) makes the determination under 35 U.S.C. 156(d)(2)(B) whether the applicant for patent term extension acted with due diligence during the regulatory review proceedings. The term "due diligence" is defined in 35 U.S.C. 156(d)(3) as "that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period." After affirming or revising the determination of the regulatory review period, the regulatory agency notifies the Office and publishes the results in the Federal Register. If no comments or petition is filed in the time period provided, the regulatory agency notifies the Office that the period for filing a due diligence petition pursuant to the notice has expired and that the regulatory agency therefore considers its determination of the regulatory review period for the product to be final. Following notification from the regulatory agency, the Office proceeds with the final eligibility determination. See 21 CFR Ch. 1, Subparts D and E.

(h) Notice of Final Determination - Calculation of Patent Term Extension

35 U.S.C. 156. Extension of patent term.

(a) The term of a patent which claims a product, a method of using a product, or a method of

manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if -

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(c) The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that-

(1) each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period;

(2) after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the periods described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g);

(3) if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraphs (1) and (2) exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years; and

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(6) A period determined under any of the preceding paragraphs is subject to the following limitations:

(A) If the patent involved was issued after the date of the enactment of this section, the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(B) If the patent involved was issued before the date of the enactment of this section and --

(i) no request for an exemption described in paragraph (1)(B) or (4)(B) was submitted and no request for the authority described in paragraph (5)(B) was submitted,

(ii) no major health or environment effects test described in paragraph (2)(B) or (4)(B) was initiated and no petition for a regulation or application for registration described in such paragraph was submitted, or

(iii) no clinical investigation described in paragraph (3) was begun or product development protocol described in such paragraph was submitted, before such date for the approved product the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(C) If the patent involved was issued before the date of the enactment of this section and if an action described in subparagraph (B) was taken before the date of the enactment of this section with respect to the approved product and the commercial marketing or use of the product has not been approved before such date, the period of extension determined on the basis of the regulatory review period determined under such paragraph may not exceed two years or in the case of an approved product which is a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act or the Virus-Serum-Toxin Act), three years.

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After reviewing the information provided by the regulatory agency, if the Office determines the patent to be eligible for extension, the calculation is made of the length of extension for which the patent is eligible under the appropriate statutory provisions (35 U.S.C. 156(c); 37 CFR 1.750). The length of extension is subject to the limitations of 35 U.S.C. 156(c)(3) and 35 U.S.C. 156(g)(6). A Notice of Final Determination is mailed to applicant which states the length of extension for which the application has been determined to be eligible and the calculations used to determine the length of extension. The notice provides a period, usually one month, in which the applicant can request reconsideration of any aspect of the Office determination as to eligibility or the length of extension for which the application has been found eligible.

If the application has been determined to be ineligible for patent term extension, an appropriate Notice of Final Determination is mailed to applicant which denies the application and sets forth the basis for the denial. The applicant is given a period, usually one month, in which to seek reconsideration of the determination.

If the patent is found to be eligible for extension, the Notice of Final Determination may include the following text:

A determination has been made that U.S. Patent No. ___, which claims the human drug ___, is eligible for patent term extension under 35 U.S.C. ' 156. The period of extension has been determined to be ___.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of ___. Under 35 U.S.C. 156(c):

Period of Extension = 2 (Testing Phase) + Approval Phase
= 2 (___ -___) + ___
= ___ days

Since the regulatory review period began __, before the patent issued ___, only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period. 35 U.S.C. 156(c). (From __ to ___ is___ days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: ___ - ___ = ___ days.) No determination of a lack of due diligence under 35 U.S.C. 156(c)(1) was made.

The 14 year exception of 35 U.S.C. 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (___) when added to the period of extension calculated above (___ days) cannot exceed fourteen years. The period of extension is thus limited to ___, by operation of 35 U.S.C. 156(c)(3). Since the patent term (35 U.S.C. 154) would expire on ___, the period of extension is the number of days to extend the term of the patent from its expiration date to and including ___, or ___ days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of ___ days.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:
Granted:
Original Expiration Date:
Applicant:
Owner of Record:
Title:
Classification:
Product Trade Name:
Term Extended:
Extended Expiration Date:

A patent term extension generally extends the patent from its "original expiration date," as defined by 35 U.S.C. 154 to include extension under 35 U.S.C. 154(b). See ' I. Patents "in force on June 8, 1995 only because of a Hatch-Waxman extension are not entitled to re-apply a restoration extension to a 20-year from filing term." *Merck & Co. v. Kessler,* 80 F.3d 1543, 1553, 38 USPQ2d 1347, 1354 (Fed. Cir. 1996). However, if the patent received an interim

extension under 35 U.S.C. 156(d)(5) and the patent is eligible for either a two- or a three-year extension, the extension would run from the approval date of the product, not the original expiration date of the patent. See 35 U.S.C. 156(d)(5)(E)(ii).

The procedure for calculating the length of the patent term extension is set forth for human drugs, antibiotic drugs, and human biological products in 37 CFR 1.775; for food or color additives in 37 CFR 1.776; for medical devices in 37 CFR 1.777; for animal drug products in 37 CFR 1.778; and for veterinary biological products in 37 CFR 1.779. The length of patent term extension is the length of the regulatory review period as determined by the Secretary of Health and Human Services, but reduced, where appropriate, by the time periods provided in 37 CFR 1.775 - 1.779. The Office will rely on the Secretary's determination of the length of the regulatory review period when calculating the length of the extension period under 37 CFR 1.775 - 1.779.

Any part of the regulatory review period which occurs before the patent was granted will not be counted toward patent term extension. Any period in which the marketing applicant failed to exercise due diligence, thereby unnecessarily adding to the length of the regulatory review period after the patent issued, will not be considered in determining the length of the extension period. In making the calculation of the extension period, half days will be ignored and thus will not be subtracted from the regulatory review period.

For products other than animal drug or veterinary biological products, the calculated extension period cannot exceed any of the following statutory maximum periods of extension:

(1) If the period remaining in the term of the patent after the date of approval of the approved product, when added to the calculated regulatory review period, exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years;

(2) If the patent involved was issued after September 24, 1984, (the date of enactment of 35 U.S.C. 156), the calculated period of extension may not exceed five years;

(3) If the patent involved was issued before September 24, 1984, (the date of enactment of 35 U.S.C. 156), and the regulatory review period proceeding started after this date, the calculated period of extension may not exceed five years; and

(4) If the patent involved was issued before September 24, 1984, (the date of enactment of 35 U.S.C. 156), and the regulatory review period proceeding started before this date, and the commercial marketing or use of the product has been approved after such date, the calculated period of extension may not exceed two years.

For animal drug or veterinary biological products, the calculated extension period cannot exceed any of the following statutory maximum periods of extension:

(1) If the period remaining in the term of the patent after the date of approval of the approved product when added to the calculated regulatory review period exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years;

(2) If the patent involved was issued after November 16, 1988, the calculated period of extension may not exceed five years;

(3) If the patent involved was issued before November 16, 1988, and the regulatory review period proceeding started after this date, the calculated period of extension may not exceed five

years; and

(4) If the patent involved was issued before November 16, 1988, and the regulatory review period proceeding started before this date, and the commercial marketing or use of the product has been approved after such date, the calculated period of extension may not exceed three years.

The term of a patent that issued before September 24, 1984, where the regulatory review period began and ended before September 24, 1984, may be extended for more than five years, but cannot exceed the 14-year limit set forth in 35 U.S.C. 156(c)(3). *Hoechst Aktiengesellschaft v. Quigg*, 916 F.2d 522, 525, 16 USPQ2d 1549, 1551 (Fed. Cir. 1990).

(i) Calculation of Patent Term Extension for a Human Drug, Antibiotic Drug or Human Biological Product

35 U.S.C. 156. Extension of patent term.

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(g) For purposes of this section, the term Aregulatory review period@ has the following meanings:

(1) (A) In the case of a product which is a new drug, antibiotic drug, or human biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a new drug, antibiotic drug, or human biological product is the sum of --

(i) the period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507 became effective for the approved product and ending on the date an application was initially submitted for such drug product under section 351, 505, or 507, and

(ii) the period beginning on the date the application was initially submitted for the approved product under section 351, subsection (b) of section 505, or section 507 and ending on the date such application was approved under such section.

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37 CFR 1.775. Calculation of patent term extension for a human drug, antibiotic drug or human biological product.

(a) If a determination is made pursuant to ' 1.750 that a patent for a human drug, antibiotic drug or human biological product is eligible for extension, the term shall be extended by the time as calculated in days in the manner indicated by this section. The patent term extension will run from the original expiration date of the patent or any earlier date set by terminal disclaimer (' 1.321).

(b) The term of the patent for a human drug, antibiotic drug or human biological product will be extended by the length of the regulatory review period for the product as determined by the Secretary of Health and Human Services, reduced as appropriate pursuant to paragraphs (d)(1) through (d)(6) of this section.

(c) The length of the regulatory review period for a human drug, antibiotic drug or human biological product will be determined by the Secretary of Health and Human Services. Under 35 U.S.C. 156(g)(1)(B), it is the sum of --

(1) The number of days in the period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507 of the Federal Food, Drug, and Cosmetic Act became effective for the approved product and ending on the date the application was initially submitted for such product under those sections or under section 351 of the Public Health Service Act; and

(2) The number of days in the period beginning on the date the application was initially submitted for the approved product under section 351 of the Public Health Service Act, subsection (b) of section 505 or section 507 of the Federal Food, Drug, and Cosmetic Act and ending on the date such application was approved under such section.

(d) The term of the patent as extended for a human drug, antibiotic drug or human biological product will be determined by C

(1) Subtracting from the number of days determined by the Secretary of Health and Human Services to be in the regulatory review period:

(i) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section which were on and before the date on which the patent issued;

(ii) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section during which it is determined under 35 U.S.C. 156(d)(2)(B) by the Secretary of Health and Human Services that applicant did not act with due diligence;

(iii) One-half the number of days remaining in the period defined by paragraph (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1)(i) and (ii) of this section; half days will be ignored for purposes of subtraction;

(2) By adding the number of days determined in paragraph (d)(1) of this section to the original term of the patent as shortened by any terminal disclaimer;

(3) By adding 14 years to the date of approval of the application under section 351 of the Public Health Service Act, or subsection (b) of section 505 or section 507 of the Federal Food, Drug and Cosmetic Act;

(4) By comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) of this section with each other and selecting the earlier date;

(5) If the original patent was issued after September 24, 1984,

(i) By adding 5 years to the original expiration date of the patent or any earlier date set by terminal disclaimer; and

(ii) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(5)(i) of this section with each other and selecting the earlier date;

(6) If the original patent was issued before September 24, 1984, and

(i) If no request was submitted for an exemption under subsection (i) of section 505 or subsection (d) of section 507 of the Federal Food, Drug and Cosmetic Act before September 24, 1984, by -

(A) Adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer; and

(B) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(i)(A) of this section with each other and selecting the earlier date; or

(ii) If a request was submitted for an exemption under subsection (i) of section 505 or subsection (d) of section 507 of the Federal Food, Drug, or Cosmetic Act before September 24, 1984 and the commercial marketing or use of the product was not approved before September 24, 1984, by -

(A) Adding 2 years to the original expiration date of the patent or earlier date set by terminal disclaimer, and

(B) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(ii)(A) of this section with each other and selecting the earlier date.

An application or petition requesting permission to commercially use or sell a product is "initially submitted on the date it contains sufficient information to allow FDA to commence review of the application. 21 CFR '60.20(f)(1994)." *Aktiebolaget Astra v. Lehman*, 71 F.3d 1578, 1579, 37 USPQ2d 1212,1213 (Fed. Cir. 1995)(emphasis in original). The Secretary of Health and Human Services, not the Commissioner of the PTO, has the authority under 35 U.S.C. 156 to determine the regulatory review period. *Astra*, 71 F.3d at 1580, 37 USPQ2d at 1214.

(ii) Calculation of Patent Term Extension for a Food Additive or Color Additive

35 U.S.C. 156. Extension of patent term.

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(g) For purposes of this section, the term Aregulatory review period@ has the following meanings:

(2) (A) In the case of a product which is a food additive or color additive, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a food or color additive is the sum of --

(i) the period beginning on the date a major health or environmental effects test on the additive was initiated and ending on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and

(ii) the period beginning on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending on the date such regulation became effective or, if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.

*****

37 CFR 1.776. Calculation of patent term extension for a food additive or color additive.

(a) If a determination is made pursuant to ' 1.750 that a patent for a food additive or color additive is eligible for extension, the term shall be extended by the time as calculated in days in the manner indicated by this section. The patent term extension will run from the original expiration date of the patent or earlier date set by terminal disclaimer (' 1.321).

(b) The term of the patent for a food additive or color additive will be extended by the length of the regulatory review period for the product as determined by the Secretary of Health and Human Services, reduced as appropriate pursuant to paragraphs (d)(1) through (d)(6) of this section.

(c) The length of the regulatory review period for a food additive or color additive will be determined by the Secretary of Health and Human Services. Under 35 U.S.C. 156(g)(2)(B), it is the sum of -

(1) The number of days in the period beginning on the date a major health or environmental effects test on the additive was initiated and ending on the date a petition was initially submitted with respect to the approved product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product; and

(2) The number of days in the period beginning on the date a petition was initially submitted with respect to the approved product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending on the date such regulation became effective or, if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.

(d) The term of the patent as extended for a food additive or color additive will be determined by

(1) Subtracting from the number of days determined by the Secretary of Health and Human Services to be in the regulatory review period:

(i) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section which were on and before the date on which the patent issued;

(ii) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section during which it is determined under 35 U.S.C. 156(d)(2)(B) by the Secretary of Health and Human Services that applicant did not act with due diligence;

(iii) The number of days equal to one-half the number of days remaining in the period defined by paragraph (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1) (i) and (ii) of this section; half days will be ignored for purposes of subtraction;

(2) By adding the number of days determined in paragraph (d)(1) of this section to the original term of the patent as shortened by any terminal disclaimer;

(3) By adding 14 years to the date a regulation for use of the product became effective or, if objections were filed to such regulation, to the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, to the date such proceedings were finally resolved and commercial marketing was permitted;

(4) By comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3)

of this section with each other and selecting the earlier date;

(5) If the original patent was issued after September 24, 1984,

(i) By adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer; and,

(ii) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(5)(i) of this section with each other and selecting the earlier date;

(6) If the original patent was issued before September 24, 1984, and

(i) If no major health or environmental effects test was initiated and no petition for a regulation or application for registration was submitted before September 24, 1984, by

(A) Adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer, and

(B) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(i)(A) of this section with each other and selecting the earlier date; or

(ii) If a major health or environmental effects test was initiated or a petition for a regulation or application for registration was submitted by September 24, 1984, and the commercial marketing or use of the product was not approved before September 24, 1984, by --

(A) Adding 2 years to the original expiration date of the patent or earlier date set by terminal disclaimer, and

(B) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(ii)(A) of this section with each other and selecting the earlier date.

The regulatory review period for a food or color additive ends on the effective date of the permission for commercial marketing or use. The effective date is stated in the regulation or order granting such permission and is often the date of publication of the regulation or order in the Federal Register. This date will generally be later than the date the approval is communicated to the marketing applicant.

(iii) Calculation of Patent Term Extension for a Medical Device

35 U.S.C. 156. Extension of patent term.

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(g) For purposes of this section, the term Aregulatory review period@ has the following meanings:

(3) (A) In the case of a product which is a medical device, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a medical device is the sum of --

(i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and

(ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

*****

37 CFR 1.777. Calculation of patent term extension for a medical device.

(a) If a determination is made pursuant to ' 1.750 that a patent for a medical device is eligible for extension, the term shall be extended by the time as calculated in days in the manner indicated by this section. The patent term extension will run from the original expiration date of the patent or earlier date as set by terminal disclaimer (' 1.321).

(b) The term of the patent for a medical device will be extended by the length of the regulatory review period for the product as determined by the Secretary of Health and Human Services, reduced as appropriate pursuant to paragraphs (d)(1) through (d)(6) of this section.

(c) The length of the regulatory review period for a medical device will be determined by the Secretary of Health and Human Services. Under 35 U.S.C. 156(g)(3)(B), it is the sum of

(1) The number of days in the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act; and

(2) The number of days in the period beginning on the date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act, and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) of the Act and ending on the date the protocol was declared completed under section 515(f)(6) of the Act.

(d) The term of the patent as extended for a medical device will be determined by --

(1) Subtracting from the number of days determined by the Secretary of Health and Human Services to be in the regulatory review period pursuant to paragraph (c) of this section:

(i) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section which were on and before the date on which the patent issued;

(ii) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section during which it is determined under 35 U.S.C. 156(d)(2)(B) by the Secretary of Health and Human Services that applicant did not act with due diligence;

(iii) One-half the number of days remaining in the period defined by paragraph (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1) (i) and (ii) of this section; half days will be ignored for purposes of subtraction;

(2) By adding the number of days determined in paragraph (d)(1) of this section to the original term of the patent as shortened by any terminal disclaimer;

(3) By adding 14 years to the date of approval of the application under section 515 of the Federal Food, Drug, and Cosmetic Act or the date a product development protocol was declared completed under section 515(f)(6) of the Act;

(4) By comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) of this section with each other and selecting the earlier date;

(5) If the original patent was issued after September 24, 1984,

(i) By adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer; and

(ii) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(5)(i) of this section with each other and selecting the earlier date;

(6) If the original patent was issued before September 24, 1984, and

(i) If no clinical investigation on humans involving the device was begun or no product development protocol was submitted under section 515(f)(5) of the Federal Food, Drug and Cosmetic Act before September 24, 1984, by --

(A) Adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer and

(B) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(i)(A) of this section with each other and selecting the earlier date; or

(ii) If a clinical investigation on humans involving the device was begun or a product development protocol was submitted under section 515(f)(5) of the Federal Food, Drug, and Cosmetic Act before September 24, 1984 and the commercial marketing or use of the product was not approved before September 24, 1984, by

(A) Adding 2 years to the original expiration date of the patent or earlier date set by terminal disclaimer, and

(B) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(ii)(A) of this section with each other and selecting the earlier date.

(iv) Calculation of Patent Term Extension for an Animal Drug Product

35 U.S.C. 156. Extension of patent term.

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(g) For purposes of this section, the term Aregulatory review period@ has the following meanings:

(4) (A) In the case of a product which is a new animal drug, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a new animal drug product is the sum of --

(i) the period beginning on the earlier of the date a major health or environmental effects test on the drug was initiated or the date an exemption under subsection (j) of section 512 became effective for the approved new animal drug product and ending on the date an application was initially submitted for such animal drug product under section 512, and

(ii) the period beginning on the date the application was initially submitted for the approved animal drug product under subsection (b) of section 512 and ending on the date such application was approved under such section.

*****

37 CFR 1.778. Calculation of patent term extension for an animal drug product.

(a) If a determination is made pursuant to ' 1.750 that a patent for an animal drug is eligible for extension, the term shall be extended by the time as calculated in days in the manner indicated by this section. The patent term extension will run from the original expiration date of the patent or any earlier date set by terminal disclaimer (' 1.321).

(b) The term of the patent for an animal drug will be extended by the length of the regulatory review period for the drug as determined by the Secretary of Health and Human Services, reduced as appropriate pursuant to paragraphs (d)(1) through (d)(6) of this section.

(c) The length of the regulatory review period for an animal drug will be determined by the Secretary of Health and Human Services. Under 35 U.S.C. 156(g)(4)(B), it is the sum of --

(1) The number of days in the period beginning on the earlier of the date a major health or environmental effects test on the drug was initiated or the date an exemption under subsection (j) of section 512 of the Federal Food, Drug, and Cosmetic Act became effective for the approved animal drug and ending on the date an application was initially submitted for such animal drug under section 512 of the Federal Food, Drug, and Cosmetic Act; and

(2) The number of days in the period beginning on the date the application was initially submitted for the approved animal drug under subsection (b) of section 512 of the Federal Food, Drug, and Cosmetic Act and ending on the date such application was approved under such section.

(d) The term of the patent as extended for an animal drug will be determined by --

(1) Subtracting from the number of days determined by the Secretary of Health and Human Services to be in the regulatory review period:

(i) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section that were on and before the date on which the patent issued;

(ii) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section during which it is determined under 35 U.S.C. 156(d)(2)(B) by the Secretary of Health and Human Services that applicant did not act with due diligence;

(iii) One-half the number of days remaining in the period defined by paragraph (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1)(i) and (ii) of this section; half days will be ignored for purposes of subtraction;

(2) By adding the number of days determined in paragraph (d)(1) of this section to the original term of the patent as shortened by any terminal disclaimer;

(3) By adding 14 years to the date of approval of the application under section 512 of the Federal Food, Drug, and Cosmetic Act;

(4) By comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) of this section with each other and selecting the earlier date;

(5) If the original patent was issued after November 16, 1988, by---

(i) Adding 5 years to the original expiration date of the patent or any earlier date set by terminal disclaimer; and

(ii) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(5)(i) of this section with each other and selecting the earlier date;

(6) If the original patent was issued before November 16, 1988, and

(i) If no major health or environmental effects test on the drug was initiated and no request was submitted for

an exemption under subsection (j) of section 512 of the Federal Food, Drug, and Cosmetic Act before November 16, 1988, by --

(A) Adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer; and

(B) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(i)(A) of this section with each other and selecting the earlier date; or

(ii) If a major health or environmental effects test was initiated or a request for an exemption under subsection (j) of section 512 of the Federal Food, Drug, and Cosmetic Act was submitted before November 16, 1988, and the application for commercial marketing or use of the animal drug was not approved before November 16, 1988, by --

(A) Adding 3 years to the original expiration date of the patent or earlier date set by terminal disclaimer, and

(B) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(ii)(A) of this section with each other and selecting the earlier date.

(v) Calculation of Patent Term Extension for a Veterinary Biological Product

35 U.S.C. 156. Extension of patent term

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(g) For purposes of this section, the term Aregulatory review period@ has the following meanings:...

(5)(A) In the case of a product which is a veterinary biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory period for a veterinary biological product is the sum of --

(i) the period beginning on the date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective and ending on the date an application for a license was submitted under the Virus-Serum-Toxin Act, and

(ii) the period beginning on the date an application for a license was initially submitted for approval under the Virus-Serum-Toxin Act and ending on the date such license was issued.

*****

37 CFR 1.779. Calculation of patent term extension for a veterinary biological product.

(a) If a determination is made pursuant to ' 1.750 that a patent for a veterinary biological product is eligible for extension, the term shall be extended by the time as calculated in days in the manner indicated by this section. The patent term extension will run from the original expiration date of the patent or any earlier date set by terminal disclaimer (' 1.321).

(b) The term of the patent for a veterinary biological product will be extended by the length of the regulatory review period for the product as determined by the Secretary of Agriculture, reduced as appropriate pursuant to paragraphs (d)(1) through (d)(6) of this section.

(c) The length of the regulatory review period for a veterinary biological product will be determined by the Secretary of Agriculture. Under 35 U.S.C. 156(g)(5)(B), it is the sum of --

(1) The number of days in the period beginning on the date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective and ending on the date an application for a license was submitted under the Virus-Serum-Toxin Act; and

(2) The number of days in the period beginning on the date an application for a license was initially submitted for approval under the Virus-Serum-Toxin Act and ending on the date such license was issued.

(d) The term of the patent as extended for a veterinary biological product will be determined by--

(1) Subtracting from the number of days determined by the Secretary of Agriculture to be in the regulatory review period:

(i) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section that were on and before the date on which the patent issued;

(ii) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section during which it is determined under 35 U.S.C. 156(d)(2)(B) by the Secretary of Agriculture that applicant did not act with due diligence;

(iii) One-half the number of days remaining in the period defined by paragraph (c)(1) of this section after that

period is reduced in accordance with paragraphs (d)(1)(i) and (ii) of this section; half days will be ignored for purposes of subtraction;

(2) By adding the number of days determined in paragraph (d)(1) of this section to the original term of the patent as shortened by any terminal disclaimer;

(3) By adding 14 years to the date of the issuance of a license under the Virus-Serum-Toxin Act;

(4) By comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) of this section with each other and selecting the earlier date;

(5) If the original patent was issued after November 16, 1988, by --

(i) Adding 5 years to the original expiration date of the patent or any earlier date set by terminal disclaimer; and

(ii) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(5)(i) of this section with each other and selecting the earlier date;

(6) If the original patent was issued before November 16, 1988, and

(i) If no request for the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act was submitted before November 16, 1988, by --

(A) Adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer; and

(B) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(i)(A) of this section with each other and selecting the earlier date; or

(ii) If a request for the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act was submitted before November 16, 1988, and the commercial marketing or use of the product was not approved before November 16, 1988, by --

(A) Adding 3 years to the original expiration date of the patent or earlier date set by terminal disclaimer; and

(B) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(ii)(A) of this section with each other and selecting the earlier date.

(i) Certificate of Extension of Patent Term

35 U.S.C. 156. Extension of patent term.

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(e) (1) A determination that a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the application for the extension. If the Commissioner determines that a patent is eligible for extension under paragraphs (1) through (4) of subsection (a) and that the requirements of subsection (d) have been complied with, the Commissioner shall issue to the applicant for the extension of the term of the patent a certificate of extension, under seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent.

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37 CFR 1.780 Certificate of extension of patent term.

If a determination is made pursuant to ' 1.750 that a patent is eligible for extension and that the term of the patent is to be extended, a certificate of extension, under seal, or a certificate or interim extension under 35 U.S.C. 156(d)(5) will be issued to the applicant for the extension of the patent term. Such certificate will be recorded in the official file of the patent and will be considered as part of the original patent. Notification of the issuance of the certificate of extension will be published in the *Official Gazette* of the Patent and Trademark Office. Notification of the issuance of the certificate of interim extension under 35 U.S.C. 156(d)(5), including the identity of the product currently under regulatory review, will be published in the *Official Gazette* of the Patent and Trademark Office and in the *Federal Register*. No certificate of extension will be issued if the term of the patent cannot be extended, even though the patent is otherwise determined to be eligible for extension. In such situations the final determination made pursuant to ' 1.750 will indicate that no certificate will issue.

Once a determination is made pursuant to 37 CFR 1.750 that a patent is eligible for extension of

its term, a certificate of extension, under seal, will be issued to the patent owner at the correspondence address specified in the application for patent term extension. Following the one-month period provided in the Notice of Final Determination, and where an extension is appropriate, the Certificate of Extension is prepared for signature by the Commissioner of Patents and Trademarks. The original is mailed or delivered to the applicant and a copy is sent to the regulatory agency. A copy of the certificate is placed in the two files (official file/patent file and public file) maintained for the application for extension. The certificate of extension includes the following text:

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE EXTENDING PATENT TERM
UNDER 35 U.S.C. ' 156

PATENT NO. :

DATED :

INVENTOR(S) :

PATENT OWNER:

This is to certify that there has been presented to the
COMMISSIONER OF PATENTS AND TRADEMARKS
an application under 35 U.S.C. 156 for an extension of the patent term. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

___ days

from, ___, the original expiration date of the patent, with all rights pertaining thereto as provided by 35 U.S.C. 156(b).

No certificate or extension will be issued if the term of a patent cannot be extended, even though the patent is otherwise determined to be eligible for extension. In such situations the final determination would issue indicating that no certificate will issue.

(j) Notice of Extension of Patent Term Published in the *Official Gazette*

A notice is also prepared and forwarded to the Office of Publication for publication in the *Official Gazette*. A sample *Official Gazette* Notice Follows:

PATENT TERM EXTENDED UNDER 35 U.S.C. 156

A Certificate extending the term of the following patent was issued on __.
U.S. Patent No.: __ Granted: __; Applicant: __; Owner of Record: __; Title: ___; Classification: __ Product Trade Name: __7; Original Expiration Date: __; Term Extended: ___; Extended Expiration Date: __.

(k) Distribution of Certificate of Extension of Patent Term

Once a determination is made pursuant to 37 CFR 1.750 that a patent is eligible for extension of its term, all original papers from the application for patent term extension in the official file are transferred to the official patent file of the subject patent and become a part of

the permanent record. A copy of the certificate is forwarded to the Office of Publications to be added to the electronic database as part of the patent record in the same manner as is a certificate of correction or a terminal disclaimer. The patent is also added to the list of patents extended under 35 U.S.C. 156, a copy of which is posted on the PTO homepage (www.uspto.gov) and which is also available in the Public Search Room and from the Special Program Law Office.

D. Trade Secret, Confidential, and Protective Order Material

There is no provision in the statute or the rules for withholding from the public any information that is submitted to the Office or the regulatory agency relating to an application for patent term extension. While one submitting such materials to the Office in relation to a pending application for patent term extension must generally assume that such materials will be made of record in the file and be made public, the Office is not unmindful of the difficulties this sometimes imposes. Proprietary or trade secret information should be submitted generally in accordance with the procedures set forth in MPEP ' 724.02. Identification of the proprietary or trade secret material should be made by page, line, and word, as necessary. The Office will not in the first instance undertake the task of determining the precise material in the application which is proprietary or trade secret information. Only the applicant is in a position to make this determination. See *In re Schering-Plough Corp.*, 1 USPQ2d 1926, 1926 (Comm=r Pat. & Tm. 1986).

The information will be maintained in secret by the Office until a certificate of patent term extension is issued. If such information was material to a determination of eligibility or any other Office responsibility under 35 U.S.C. 156, it will be made public at the time the certificate of extension is issued. Otherwise, if a suitable petition to expunge is filed before the issuance of the certificate, the trade secret or confidential information will be expunged from the file and returned to the patent term extension applicant. If a petition to expunge is not filed prior to the issuance of the certificate, all of the information will be open to public inspection.

E. Multiple Applications for Extension of Term of the Same Patent or of Different Patents for the Same Regulatory Review Period for a Product

35 U.S.C. 156. Extension of patent term.

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(c)The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that-

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(4) in no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product.

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37 CFR 1.785. *Multiple applications for extension of term of the same patent or of different patents for the same regulatory review period for a product.*

(a) Only one patent may be extended for a regulatory review period for any product 1.720 (h)). If more than one application for extension of the same patent is filed, the certificate of extension of patent term, if appropriate, will be issued based upon the first filed application for extension.

(b) If more than one application for extension is filed by a single applicant which seeks the extension of the term of two or more patents based upon the same regulatory review period, and the patents are otherwise

eligible for extension pursuant to the requirements of this subpart, in the absence of an election by the applicant, the certificate of extension of patent term, if appropriate, will be issued upon the application for extension of the patent term having the earliest date of issuance of those patents for which extension is sought.

(c) If an application for extension is filed which seeks the extension of the term of a patent based upon the same regulatory review period as that relied upon in one or more applications for extension pursuant to the requirements of this subpart, the certificate of extension of patent term will be issued on the application only if the patent owner or its agent is the holder of the regulatory approval granted with respect to the regulatory review period.

(d) An application for extension shall be considered complete and formal regardless of whether it contains the identification of the holder of the regulatory approval granted with respect to the regulatory review period. When an application contains such information, or is amended to contain such information, it will be considered in determining whether an application is eligible for an extension under this section. A request may be made of any applicant to supply such information within a non-extendable period of not less than one (1) month whenever multiple applications for extension of more than one patent are received and rely upon the same regulatory review period. Failure to provide such information within the period for response set shall be regarded as conclusively establishing that the applicant is not the holder of the regulatory approval.

(e) Determinations made under this section shall be included in the notice of final determination of eligibility for extension of the patent term pursuant to ' 1.750 and shall be regarded as part of that determination.

Only one patent may be extended for a regulatory review period for any product. If more than one application for extension is filed for a single patent by different applicants, the certificate of extension of the term of the patent, if appropriate, would be issued based upon the first filed application for extension of patent term. If a single applicant files more than one application for patent term extension for a single patent based upon the regulatory review period of different products, then the final determination under 37 CFR 1.750 will provide a period of time (usually one month) for the patent owner to elect the product for which extension is desired. An express withdrawal of the applications for extension of the nonelected products should accompany the election. The final determination will state that the result of a failure of the patent owner to elect a single product within the set time period will be issuance of a certificate of extension for the patent for a specified one of the products.

If applications are filed by a single applicant for extensions of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension will be issued on the application for extension of the patent having the earliest date of issuance of those for which extension is sought, unless all but a single application for the extension of one patent term is voluntarily withdrawn by the applicant. When plural patents are found to be eligible for patent term extension based on the same regulatory review of a product, the final determination under 37 CFR 1.750 will provide a period of time (usually one month) for the patent owner to elect the patent for which extension is desired. An express withdrawal of the applications for extension of the nonelected patents should accompany the election. A failure to elect within the set time period will result in issuance of a certificate of extension for the patent having the earliest date of issue.

If applications are filed by different applicants for extension of the terms of different patents based upon the same regulatory review period of a product, the certificate of extension will be issued on the application of the holder of the regulatory approval (marketing applicant). If the marketing applicant is not an applicant for extension, the certificate of extension will issue to the applicant for extension which holds an express authorization from the marketing applicant to rely upon the regulatory review period as the basis for the application for extension.

An application for extension will be considered complete and formal regardless of whether it contains (1) the identification of the marketing applicant or (2) the express and

exclusive authorization from the marketing applicant to rely on the regulatory review period for extension. A request may be made of any applicant for extension to supply such information regarding the authorization on which applicant relies from the marketing applicant of the regulatory approval on which the application for extension is based. The failure to provide such information within the period for response shall be regarded as conclusively establishing that the applicant for extension is not the marketing applicant and is not authorized by the marketing applicant to seek the extension being sought.

F. Duty of Disclosure in Patent Term Extension Proceedings

37 CFR 1.765. Duty of disclosure in patent term extension proceedings.

(a) A duty of candor and good faith toward the Patent and Trademark Office and the Secretary of Health and Human Services or the Secretary of Agriculture rests on the patent owner or its agent, on each attorney or agent who represents the patent owner and on every other individual who is substantively involved on behalf of the patent owner in a patent term extension proceeding. All such individuals who are aware, or become aware, of material information adverse to a determination of entitlement to the extension sought, which has not been previously made of record in the patent term extension proceeding must bring such information to the attention of the Office or the Secretary, as appropriate, in accordance with paragraph (b) of this section, as soon as it is practical to do so after the individual becomes aware of the information. Information is material where there is a substantial likelihood that the Office or the Secretary would consider it important in determinations to be made in the patent term extension proceeding.

(b) Disclosures pursuant to this section must be accompanied by a copy of each written document which is being disclosed. The disclosure must be made to the Office or the Secretary, as appropriate, unless the disclosure is material to determinations to be made by both the Office and the Secretary, in which case duplicate copies, certified as such, must be filed in the Office and with the Secretary. Disclosures pursuant to this section may be made to the Office or the Secretary, as appropriate, through an attorney or agent having responsibility on behalf of the patent owner or its agent for the patent term extension proceeding or through a patent owner acting on his or her own behalf. Disclosure to such an attorney, agent or patent owner shall satisfy the duty of any other individual. Such an attorney, agent or patent owner has no duty to transmit information which is not material to the determination of entitlement to the extension sought.

(c) No patent will be determined eligible for extension and no extension will be issued if it is determined that fraud on the Office or the Secretary was practiced or attempted or the duty of disclosure was violated through bad faith or gross negligence in connection with the patent term extension proceeding. If it is established by clear and convincing evidence that any fraud was practiced or attempted on the Office or the Secretary in connection with the patent term extension proceeding or that there was any violation of the duty of disclosure through bad faith or gross negligence in connection with the patent term extension proceeding, a final determination will be made pursuant to ' 1.750 that the patent is not eligible for extension.

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A duty of candor and good faith toward the Patent and Trademark Office, the Secretary of Health and Human Services, and the Secretary of Agriculture rests on the patent owner or its agent, on each attorney or agent who represents the patent owner and on every other individual who is substantively involved on behalf of the patent owner in a patent term extension proceeding. All such individuals who are aware, or become aware, of material information adverse to a determination of entitlement to the extension sought, which has not been previously made of record in the patent term extension proceeding, must bring such information to the attention of the Office or the Secretary, as appropriate, as soon as it is practicable to do so after the individual becomes aware of the information. Information is "material" where there is a substantial likelihood that the Office or the Secretary would consider it important in determinations to be made in the patent term extension proceeding.

A copy of each written document being disclosed should accompany the disclosure.

The disclosure should be submitted to the Commissioner of Patents and Trademarks, the Secretary of Health and Human Services, or the Secretary of Agriculture, as appropriate. Such disclosures may be made through a patent attorney or agent.

A determination of eligibility for an extension or the issuance of a certificate will not be made if clear and convincing evidence of fraud or attempted fraud on the Office or a Secretary is determined to be present, or the duty of disclosure is determined to have been violated through bad faith or gross negligence in connection with the patent term extension proceeding. Since the determination as to whether a patent is eligible for extension may be made solely on the basis of the representations made in the application for extension, a final determination to refuse a patent term extension because of fraud or a violation of the duty of disclosure is expected to be rare. See MPEP ' 2010.

G. Limitation of Third Party Participation

37 CFR 1.765. Duty of disclosure in patent term extension proceedings.

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(d) The duty of disclosure pursuant to this section rests on the individuals identified in paragraph (a) of this section and no submission on behalf of third parties, in the form of protests or otherwise, will be considered by the Office. Any such submissions by third parties to the Office will be returned to the party making the submission, or otherwise disposed of, without consideration by the Office.

Although the statute specifically provides for public input into the determination of the regulatory review period, i.e., the filing of a due diligence petition before the regulatory agency, no such provision was made for proceedings before the Patent and Trademark Office. Since applicant already has a duty of disclosure to both the Office and the regulatory agency, and Congress expected that it would be an administratively simple proceeding, no input from third parties is permitted. Absent an invitation from the Commissioner, any such submission would be inappropriate. Accordingly, 37 CFR 1.765(d) precludes submissions to the Patent and Trademark Office by or on behalf of third parties, thereby making patent term extension proceedings in the Office an ex parte matter between the patent owner or its agent and the Office . Submissions by third parties not requested by the Office will be returned, or otherwise disposed of, without consideration. See *In re Dubno*, 12 USPQ2d 1153, 1154 (Comm'r Pat. & Tm. 1989).

H. Express Withdrawal of Application for Extension of Patent Term

37 CFR 1.770. Express withdrawal of application for extension of patent term.

An application for extension of patent term may be expressly withdrawn before a determination is made pursuant to ' 1.750 by filing in the Office, in duplicate, a written declaration of withdrawal signed by the owner of record of the patent or its agent. An application may not be expressly withdrawn after the date permitted for response to the final determination on the application. An express withdrawal pursuant to this section is effective when acknowledged in writing by the Office. The filing of an express withdrawal pursuant to this section and its acceptance by the Office does not entitle applicant to a refund of the filing fee (' 1.20(j)) or any portion thereof.

Any request for withdrawal after a determination has been made pursuant to 37 CFR 1.750 must be accompanied by a petition under 37 CFR 1.182 with the appropriate petition

filing fee.